UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

NEW YORK STATE RESTAURANT ASSOCIATION,

No. 08 Civ 1000 (RJH)

Plaintiff,

-against-

NEW YORK CITY BOARD OF HEALTH, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, and Thomas R. Frieden, In His Official Capacity as Commissioner Of the New York City Department of Health And Mental Hygiene, DECLARATION OF THOMAS R. FRIEDEN

Defendants.

THOMAS R. FRIEDEN, M.D., M.P.H., hereby declares under penalty of perjury:

- 1. I am the Commissioner of the Department of Health and Mental Hygiene (the "Department") of the City of New York and the Chairman of the New York City Board of Health (the "Board"), the defendants in this matter. I have held both of these positions since 2002. A copy of my *curriculum vitae* is attached hereto as Exhibit 1. I participated in all aspects of identifying the need for and adopting New York City Health Code §81.50 ("Calorie Posting") and I am submitting this declaration in opposition to the plaintiff's motion for declaratory relief and a preliminary injunction. A copy of New York City Health Code §81.50 is attached hereto as Exhibit 2.
- 2. Pursuant to §556 of the New York City Charter ("Charter"), and as noted in Plaintiff's Memorandum of Law, the Department is charged with regulating all matters affecting health in the City of New York. This responsibility has included, for many decades, supervising and regulating the City's food service establishments, Charter §556(8). The Department enforces provisions of the New York City Health Code (the

"Health Code"), codified in Title 24 of the Rules of the City of New York, and other applicable laws regulating service of food directly to consumers in New York City, including food that is commercially prepared, and sold or distributed for free, in food service establishments, a broad category that includes restaurants, which are important sources of daily food intake in New York City.

Obesity is epidemic in the U.S. and in New York City

3. An obesity epidemic currently undermines the health of many Americans in general and New Yorkers specifically. According to measured height and weight data from the National Health and Nutrition Examination Survey (NHANES), the obesity rate among U.S. adults more than doubled over the past three decades. While 14.5 % of Americans were obese in 1971-1974, the proportion rose to 32.2 % by 2003-2004.

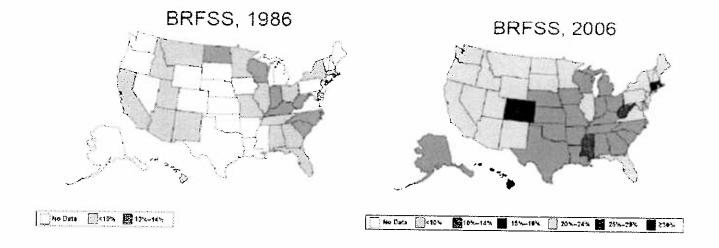
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¹ Obesity is defined as a body mass index (BMI) of 30 or higher, or about 30 pounds overweight for a 5'4" person. BMI is a number calculated from a person's weight and height (kg/m²) and is used to screen for weight categories that may lead to health problems.

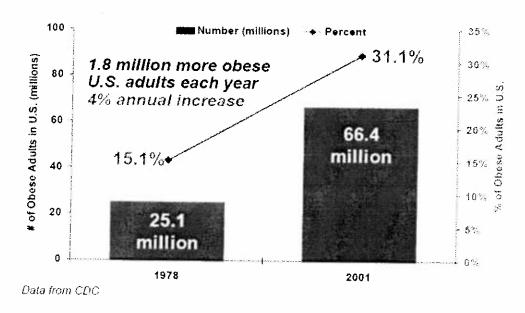
Source: http://www.cdc.gov/nccdphp/dnpa/bmi/adult_BMI/about_adult_BMI.htm; accessed June 28, 2007. Ogden CL, Carroll MD, Curtin LR, McDowell MA, Tabak CJ, Flegal KM. Prevalence of overweight and obesity in the United States, 1999-2004. JAMA 2006; 295:1549-1555.

Obesity Trends* Among U.S. Adults

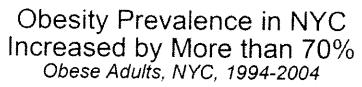
(*BMI ≥30, or ~ 30 lbs. overweight for 5' 4" person)

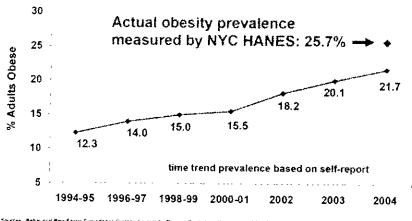


Obesity is Epidemic in the U.S.



In New York City, more than half of adults report being overweight (34.4%) or obese (21.7%).³ Obesity has been increasing rapidly over at least the past decade.





4. Studies show that by 1994-1996, an estimated one third of daily caloric intake for all Americans came from foods purchased outside of the home, and that this proportion had nearly doubled in less than 20 years.4 Although federally mandated nutrition labeling on food products for sale in supermarkets facilitates informed choice for meals eaten at home, consumers lack such essential information when eating in restaurants. This information gap constitutes a significant barrier to healthy food choices⁵ and is a key reason the Department has promoted the posting of calorie information as one means to address obesity.

³ NYC DOHMH. Community Health Survey. http://query1.health.nycnet/query/. Accessed February 7,

⁴ Guthrie JF. et al. Role of Food Prepared Away from Home in the American Diet, 1977-78 Versus 1994-96: Changes and Consequences. J Nutr Educ Behav 2002; 34(3):140-150.

⁵ U.S. Food and Drug Administration (FDA) and Center for Food Safety and Applied Nutrition (CFSAN). Counting Calories: Report of the Working Group on Obesity," 2004. http://www.cfsan.fda.gov/~dms/owgtoc.html (accessed June 28, 2007).

- 5. In December 2006, after receiving overwhelming support for the proposal in the public comment period, the Board of Health voted unanimously to adopt §81.50 of the Health Code mandating that restaurants which had already published calorie information post such information at the point of purchase to enable New Yorkers to make more informed dining choices. In September, 2007, this Court held that Health Code §81.50, as adopted, was preempted by 21 U.S.C §343-1(5) because, to the extent it applied only to restaurants which had voluntarily provided calorie information, it impermissibly regulated nutrient content claims.
- 6. Although this Court held that §81.50 was preempted because of the way it was drafted, its decision recognized that the National Labeling and Education Act ("NLEA") generally does not preempt local governments from mandating that restaurants disclose nutritional information to their customers.
- 7. Accordingly, in October 2007, the Department proposed that the Board of Health repeal and reenact Health Code §81.50. The reenacted version of §81.50 requires that chain restaurants having 15 or more outlets nationally post calorie information on menus and menu boards for menu items that are served in portions, the size and content of which are standardized. On January 22, 2008, again after receiving strong public support for the proposal in the public comment period, the Board of Health voted unanimously to adopt the new §81.50.
- 8. The Board took this step because the Board and Department are charged with the prevention and control not just of communicable diseases, but also of chronic diseases and their risk factors. Calorie posting will allow New Yorkers to make the healthy choices needed to prevent or manage chronic diseases associated with obesity. Heart

disease, stroke, cancer and diabetes constituted four of the five leading causes of death in New York City in 2006, claiming 38,337 lives (69.2% of all deaths); these are all conditions that are significantly more prevalent among persons who are obese. Obesity and diabetes are epidemic in New York City. They now generate a higher toll of preventable human suffering and use more of society's resources than even the most prevalent communicable diseases.

- 9. Every era in public health carries its own challenges. I, my colleagues on the Board of Health, and the rest of the Department take great pride in the historically significant and innovative approaches this Department and the Board of Health have taken to address past public health challenges. In 1896, New York City was the first to require reporting of tuberculosis cases and to establish effective control of that disease. In 1960, eighteen years before the Federal government acted, the Board of Health limited the use of lead-based paint in the interior of this City's residential premises. In 1970, the Board adopted Health Code §173.13, which requires the Department to conduct environmental inspections of homes of lead poisoned children and order the abatement of components covered with lead-based paint. These measures, coupled with the elimination of lead from gasoline, have resulted in steady and dramatic declines in the number of lead poisoned children in the City. More recently, in 2006, the Board of Health established stronger requirements for physical activity and nutrition in the City's day care facilities to reduce the prevalence of childhood obesity.
- 10. With respect to calorie posting, we chose to focus on calorie information because it is, by far, the most important nutrition information for diners to have when making food choices with the intent of controlling body weight. By mandating that

⁶ Bureau of Vital Statistics. NYC DOHMH. Summary of Vital Statistics 2006: The City of New York.

calories be posted on menus and menu boards, §81.50 will allow New Yorkers dining in chain restaurants to make more informed choices that can decrease their risk for the severe negative health effects associated with obesity. These issues are discussed in greater detail below, as are the specific allegations of the various declarations attached to plaintiffs' complaint.

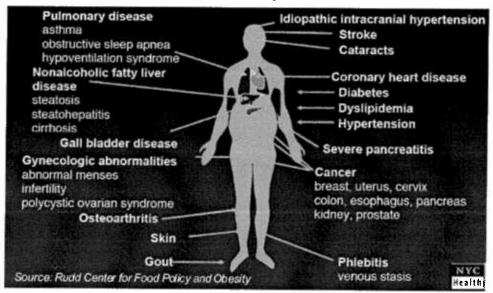
Obesity affects New York City adults and children and is responsible for a wide range of serious health problems

11. Obesity, and with it diabetes, are the only life-threatening health problems that are growing rapidly worse both in New York City and nationally. People who are overweight or obese are at increased risk for type 2 diabetes, heart disease, stroke, arthritis, gall bladder disease, osteoarthritis, sleep apnea, respiratory problems, depression, and colon, breast, endometrial, and prostate cancers. Obesity and overweight in adulthood are associated with large decreases in life expectancy.⁷ According to the Surgeon General of the United States: "Unhealthy dietary habits and sedentary behavior together account for approximately 300,000 deaths every year."8 Attached hereto as Exhibit 3 is the Surgeon General's Call to Action report.

⁷ Peeters A, Barendregt JJ, Willekens F, Mackenbach JP, Al Mamun A, Bonneux L. Overweight and obesity by middle age are associated with a shortened lifespan. Ann Intern Med 2003; 138:24-32.

⁸ U.S. Department of Health and Human Services. The Surgeon General's call to action to prevent and decrease overweight and obesity. [Rockville, MD]: U.S.Department of Health and Human Services, Public Health Service, Office of the Surgeon General; [2001].

Medical Complications of Obesity Almost every organ system is affected



Obesity and diabetes are twin epidemics with devastating health consequences

12. The prevalence of diabetes in NYC has more than doubled over the past decade, with 700,000 New Yorkers now affected.⁹ Among those with diabetes, 80% are overweight or obese.¹⁰ More than 9%, or more than half a million (540,000) adult New Yorkers have diagnosed diabetes, and another 207,000 have it and do not know.¹¹ About 23.5%, or 1.3 million, New Yorkers have higher than normal fasting blood sugars that, while not in the range of diabetes, put them at high risk for developing diabetes.¹² This

⁹ Thorpe LE, Mostashari F, Berger DK, Cobb LK, Helgerson SD, Frieden TR. Diabetes is Epidemic. NYC Vital Signs NYCDOHMH. 2003:2(1).

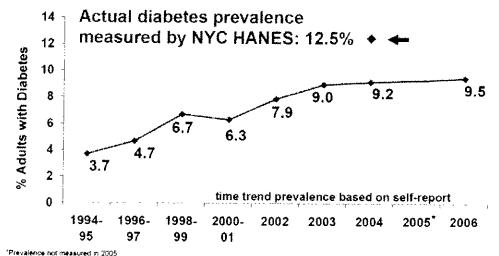
¹⁶ NYC DOHMH Community Health Survey 2006 (unpublished data).

¹¹ NYC DOHMH Community Health Survey 2006 (unpublished data) and NYC Health and Nutrition Examination Survey 2004.

¹² NYCDOHMH, More than 100,000 New Yorkers face complications due to seriously out-of-control diabetes. Unprecedented Door-to-Door Survey Finds that One Third of New Yorkers with Diabetes Do Not Know they Have the Disease, Press Release, January 30, 2007.

condition, known as impaired fasting glucose, is closely linked to overweight and obesity.

Diabetes Prevalence in NYC More than Doubled in the Past Decade Adults with Diabetes, NYC, 1994-2006



rievalence not measured in 2005
Sources Thore EE Motsesher F, Berger DK, Cobb LK. Heigerson SO. Prieden TR. Diabetes It Epidemic NYC Vital Signs 2003 2(1):1–4 (BRESS 1994-2001. NYC CHS 2002). NYC Community Health Survey. New York City Department of Health and Mental Hyghere. 2002-2004. 2005. NYC Health and Notrition Exerciseston.
Survey. New York City Department of Health and Mental Hyghere. 2004.

13. Diabetes has devastating complications. In 2003, there were about 22,492¹³ hospitalizations and about 1,819 deaths in New York City, with diabetes as the underlying cause of death, making it the fourth leading cause of death, up from sixth in 2002.¹⁴ Hospitalizations for long-term complications of diabetes have been rising steadily. In 2004, there were 4,865 people on dialysis or receiving kidney transplants in New York City due to diabetes.¹⁵ There were 3,040 lower extremity amputations in 2005

¹⁴ Kim M, Berger D, Matte T. *Diabetes in NYC: Public Health Burden and Disparities*. New York: New York City Department of Health and Mental Hygiene.2007.

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¹³ SPARCS hospital discharge data 2003.

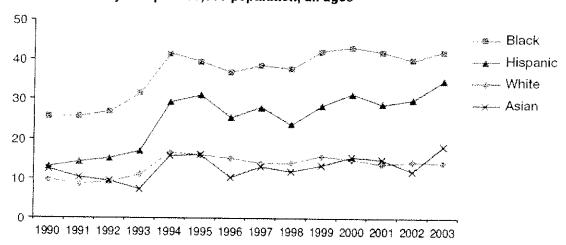
¹⁵ Kim M, Berger D, Matte T. Diabetes in NYC: Public Health Burden and Disparities. New York: New York City Department of Health and Mental Hygiene. 2007.

due to diabetes. 16 We estimate that approximately 9,000 New Yorkers have been blinded by diabetes, 17 and that more than 100,000 New Yorkers with diabetes have eye damage from diabetes. 18 Attached hereto as Exhibit 4 is the Department's report "Diabetes in New York City: Public Health Burden and Disparities."

Document 33

Mortality rates from diabetes are increasing in all racial/ethnic groups, though most rapidly in Hispanics

Diabetes mortality rate per 100,000 population, all ages



Rates are age-adjusted to the year 2000 U.S. Standard Population. Sources: Bureau of Vital Statistics, NYC DOHMH, 1990-2003; U.S. Census 2000/NYC Department of City Planning

Health care costs from obesity and diabetes are high

14. This epidemic is also generating extraordinary financial costs to society. A 2002 study by the American Diabetes Association estimates that direct and indirect costs

¹⁶ New York State Department of Health. Statewide Planning and Research Cooperative System. Albany,

M El-Hashimy, MD, K Alich, MS. Blindness caused by diabetes--Massachusetts, 1987-1994. MMWR Morb Mortal Wkly Rep. 1996 Nov 1;45(43):937-41

¹⁸ Estimates based on NYCHANES 2004, unpublished data in conjunction with data from M. El-Hashimy et al.

of diabetes were \$132 billion. 19 These sums are far larger if other obesity-related diseases and lost productivity are taken into account. Health care spending among people who are obese has been estimated to be 37% higher than among those with normal weight, and increases in the proportion of and spending on obese people relative to people of normal weight accounted for 27% of the rise in inflation-adjusted per capita health care spending between 1987 and 2001.²⁰ These increased costs are borne by families, employers and taxpayers.

Excess caloric intake drives the obesity epidemic.

15. Experts agree that the extraordinarily rapid population-level weight gain that has occurred over the past three decades is a result of the changing environment, rather than biology. The current environment in the U.S. encourages over-consumption of calories, for example, through increasingly large portions of foods and beverages that are energy-dense, easily available, and inexpensive.²¹

16. While increasing weight results from an imbalance between calories consumed (nutrition) and energy expended (physical activity), it is clear that "rising obesity is primarily the result of consuming more calories."22 Unburned calories are stored as fat, regardless of whether the calories come from fats, carbohydrates or proteins. Studies of dietary intake in the United States have found that people are eating more calories in contrast to other aspects of dietary intake (other than salt), which have

¹⁹ American Diabetes Assn., "Economic Costs of Diabetes in the U.S. in 2002." Diabetes Care, v.26, n.3. March 2003.

Thorpe KE, Florence CS, Howard DH, Joski P. The impact of obesity on rising medical spending. Health Aff (Millwood). 2004 Jul-Dec; Suppl Web Exclusives: W4-480-6.

Hill JO, Wyatt HR, Reed GW, Peters JC. Obesity and the environment: where do we go from here? Science 2003; 299(5608):853-5.

²² Bleich S, Cutler D, Murray C, Adams A. Why is the developed world obese? NBER Working Paper # 12954;2007. http://www.nber.org/papers/w12954

improved.²³ Furthermore, when calorie consumption decreases, for example through a reduction in portion size, reduction in other unhealthy nutrients, such as saturated fat or sodium, also frequently occur, as evidenced by the chains own published information for varying portion sizes.²⁴

17. For this reason, calories are recognized as the single most important element of nutrition information needed to address the obesity epidemic, and the highest priority focus of regulations to require such nutrition information. The Food and Drug Administration's Obesity Working Group ("OWG") concluded its 2005 work with a report entitled "Calories Count"25 in which the executive summary noted that recommendations were "centered on the scientific fact that weight control is primarily a function of balance of the calories eaten and calories expended on physical and metabolic activity.... The recommendations contained in this report therefore focus on a "calories count" emphasis for FDA actions....." Attached hereto as Exhibit 5 is the FDA and Center for Food Safety and Applied Nutrition report, "Calories Count."

18. Even modest reductions in calorie intake can dramatically improve health. A reduction of 300 calories twice per week (the difference between a large diet and a sugarsweetened soda) could result in a weight loss of more than 8 pounds in a year. This is equivalent to the weight loss documented in a landmark study which found that progression to diabetes from pre-diabetes was reduced 58% in people who received a

²³ Lee S, Harnack L, Jacobs DR, Steffen LM, Arnett DK. Trends in diet quality for coronary heart disease prevention between 1980-82 and 2000-2002: The Minnesota Heart Survey. J Am Diet Assoc. 2007: 107(2): 213-22.

²⁴McDonald's Nutrition Facts. http://www.mcdonalds.com/app_controller.nutrition.index1.html. Accessed February 7, 2008.

²⁵ U.S. Food and Drug Administration (FDA) and Center for Food Safety and Applied Nutrition (CFSAN). Calories Count: Report of the Working Group on Obesity," 2004. http://www.cfsan.fda.gov/~dms/owgtoc.html (accessed June 28, 2007).

lifestyle support program and underwent moderate weight loss and modest increases in physical activity.²⁶ If the 1.3 million New Yorkers with pre-diabetes were to achieve these modest changes, at least 188,000 cases of diabetes would be prevented over the next three years, avoiding the resultant burden of heart disease, blindness, kidney failure and amputations.

Document 33

19. Calorie posting in restaurants is a strategy designed to increase awareness of energy intake by making information available at point of purchase. However, contrary to the many claims in the declarations submitted in support of plaintiff's motion and to the arguments in plaintiff's Memorandum of Law, restaurants are in no way prevented by Health Code §81.50 from providing additional nutrient information (such as sodium, saturated fat or carbohydrates) to their customers.

Rapidly increasing portion sizes contribute to elevated caloric intake

20. Studies have documented patterns of increasing portion sizes, particularly at fast-chain restaurants, since the 1970s, in a pattern that parallels the epidemic of obesity.^{27,28,29,30,31} On average, portion sizes and energy intake increased for soft drinks by 49 calories, for French fries by 68 calories, and for hamburgers by 97 calories per

²⁶ Diabetes Prevention Program Research Group. Reduction in the Incidence of Type 2 Diabetes with Lifestyle Intervention or Metformin. J Med. 2002; 346: 393-403.

²⁷ Nielsen, S. J., and B. M. Popkin. Patterns and trends in food portion sizes, 1977-1998. JAMA 2003; 289(4):450-453.

²⁸ Young, L. R. and M. Nestle. The Contribution of Expanding Portion Sizes to the US Obesity Epidemic. American Journal of Public Health 2002; 92(2):246-249.

Guthrie, J. F., B. H. Lin, and E. Frazao. Role of food prepared away from home in the American diet. 1977-78 versus 1994-96: Changes and consequences. Journal of Nutrition Education and Behavior 2002; 34(3):140-150.

Ello-Martin, J. A., J. H. Ledikwe, and B. J. Rolls. The Influence of Food Portion Size and Energy Density on Energy Intake: Implications for Weight Management. The American Journal of Clinical Nutrition 2005; 82(1 Suppl.):236S-241S.

³¹ Young L.R. and Nestle M. Portion Sizes and Obesity: Responses of Fast-Food Companies. Journal of Public Health Policy 2007; 28: 238-248.

serving.³² Even small changes, e.g., eating just 10 more calories per day over the course of a year, can result in weight gain of one pound; the potential impact of increases in portion size ranging from 50 to 100 calories is even more dramatic. Attached hereto as Exhibit 6 is the report by Nielsen and Popkin, "Patterns and trends in food portion sizes, 1977-1998," published in the Journal of the American Medical Association.

An increasing proportion of calories is being consumed away from home

21. Eating out, and eating extra calories while eating out, contributes disproportionately to the excess calorie intake that fuels the obesity epidemic. 33,34 Increasingly, Americans are eating meals away from home. In 1970, Americans spent 26% of their food dollars on foods prepared outside their homes, while by 2006, they spent almost half (48%) of their food dollars eating out. In 1994-1996, the average American consumed about one third of calories from foods prepared outside of the home, up from 18% less than 20 years earlier. Children eat almost twice as many calories when they eat out than when they eat at home. This trend has been facilitated by the increasing number of chain restaurants, which serve food that is easily available, inexpensive and high in calories. Nationally, restaurant chains – both fast food and casual dining chains – comprise a growing share of customer traffic. Between 2005 and 2009,

 $^{^{32}}$ Nielsen, S. J., and B. M. Popkin. Patterns and trends in food portion sizes, 1977-1998. JAMA 2003; $289(4){:}450{-}453.$

³³ St-Onge MP, Keller KL, Heymsfield SB. Changes in childhood food consumption patterns: a cause for concern in light of increasing body weights. *American Journal of Clinical Nutrition* 2003; 78:1068-1073 ³⁴ French SA, Harnack L, Jeffery RW. Fast food restaurant use among women in the Pound of Prevention study: dietary, behavioral and demographic correlates. *International Journal of Obesity* 2000. 24:1353-1359.

³⁵ National Restaurant Association (NRA). "Industry at a Glance." 2005.

³⁶ Guthrie JF. et al. Role of Food Prepared Away from Home in the American Diet, 1977-78 Versus 1994-96: Changes and Consequences. *Society for Nutrition Education* 2002; 34:140-150.

³⁷ Zoumas-Morse C. et al. Children's Patterns of Macronutrient Intake and Associations with Restaurant and Home Eating" Journal of the American Dietetic Association 2001. 101:923-925.

³⁸ NPD Group. Overview of Foodservice Industry (undated)

the number of fast food establishments is projected to increase from 266,300 to 287,437 establishments.³⁹

Away-from-home meals such as those served at chain restaurants are higher in calories than meals consumed at home

- 22. Meals eaten away from home are associated with increased calorie intake. Despite Dr. Allison's allegation that the "evidence submitted in favor of the unique role of restaurants as contributing to the obesity epidemic is strictly observational, and more importantly, equivocal", the evidence that restaurant and fast food are the fastest growing component of the national increase in caloric intake is incontrovertible. The nationwide Food Consumption Survey revealed that energy (calorie) intake from restaurant/fast food as a percentage of total energy intake doubled (+90%) between 1977 and 1996, as national caloric intake increased for Americans over age 2 by nearly 200 calories per day, from 1,791 to 1,983 calories. Restaurants and fast food were the fastest growing source of calories in this period, while calories from food at home fell.⁴⁰ Attached hereto as Exhibit 7 is the study by Nielsen, Siega-Riz & Popkin, "Trends in energy intake in the United States between 1977-1996." While the studies that relate fast food intake or food away from home directly to obesity are observational, the key conclusions that Americans are eating more, and that much of that increase comes from restaurants and fast food, are clear.
- 23. There are abundant data to show that people who eat at fast food establishments consume more calories. Two important analyses draw on the Continuing

³⁹ C. Barnes & Co. 2008 Barnes reports: U.S. Fast Foods Restaurants Industry (NAICS 72221), 2007.

⁴⁰ Nielsen SJ, Siega-Riz AM, Popkin BM. Trends in energy intake in the United States between 1977-1996: Similar shifts seen across all age groups. Obesity Res 10:370-378 (2002)

Surveys of Food Intakes conducted in the mid 1990s. The first, a 1994-1996 survey of 17,370 adults and children, found that adults who ate at fast food restaurants consumed 205 more calories per day than those who did not, and children ate 155 more calories.⁴¹ In the second survey, of more than 9,000 adults, mean energy intake on days when fast food was consumed was 206 calories higher than on other days.⁴² This increase in calories would result in a three pound weight gain each year if a consumer were to eat fast food only once each week. In the second survey, fast food contributed more than one third of consumers' daily calorie intake. 43 Similarly, in a study of nearly 900 women. called Pound of Prevention, increased frequency of eating at fast food restaurants was associated with higher total energy intake.⁴⁴ This association has also been shown among adolescents and children. A study of 4,746 students age 11-18 years found that regular fast food consumption was associated with 800 extra calories per week in boys and 660 extra calories per week in girls.⁴⁵ Such a calorie excess could translate into a weight gain of 10 pounds or more per year. An increase of 129 calories per day among high- versus low-frequency consumers of fast food was also reported in a large national cohort of adolescent girls.46

⁴¹ Paeratakul S, Perdinand D, Champagne C, Ryan D, Bray G. Fast-food consumption among US adults and children: dietary and nutrient intake profile. Journal of American Dietetic Association 2003; 103(10):1332-1338.

⁴² Bowman S, Vinyard B. Fast food consumption of US adults: impact on energy and nutrient intakes and overweight status. Journal of the American College of Nutrition 2004; 23(2):163-168.

⁴³ Bowman S, Vinyard B. Fast food consumption of US adults: impact on energy and nutrient intakes and overweight status. Journal of the American College of Nutrition 2004; 23(2):163-168.

⁴⁴ French SA, Harnack L, Jeffery RW. Fast food restaurant use among women in the Pound of Prevention study: dietary, behavioral and demographic correlates. International Journal of Obesity 2000. 24:1353-1359.

⁴⁵ French SA, Story M, Neumark-Sztainer D, Fulkerson JA & Hannan P. Fast food restaurant use among adolescents: associations with nutrient intake, food choices and behavioral and psychosocial variables. International Journal of Obesity, 2001; 25: 1823-33.

⁴⁶ Schmidt M, Affenito SG, Striega-Moore R, Khoury PR, Barton B, Crawford P, Kronsberg S, Schreiber G, Obarzanek E, Daniels S. Fast-food intake and diet quality in black and white girls: the National Heart,

Chains serve food the consumption of which is associated with weight gain and obesity

24. Many studies document that the increased calorie intake observed with consumption of fast food results in weight gain in both children and adults. ^{47,48,49} In a study of more than 9,000 adults, eating fast food increased the prevalence of overweight by 27-31%; ⁵⁰ among 3,394 adults in the Coronary Artery Risk Development in Young Adults Study (CARDIA), fast food eating was positively associated with Body Mass Index (BMI), a key measure of obesity, and higher levels of fast food consumption correlated with a higher BMI. This same association has been found in different contexts, for example among Mexican children in San Diego, where 4-7-year-old children were twice as likely to be obese if they ate in fast food restaurants, ⁵¹ and among Minnesota secondary school students. ⁵² Follow-up studies further strengthen the evidence for a causal association between eating fast food and weight gain. In a study of 3,031 adults (part of CARDIA) who were followed up for 15 years, baseline fast food intake was directly associated with increases in body weight. ⁵³ Similarly, in a study of almost

Lung, and Blood Institute Growth and Health Study. Archives of Pediatrics & Adolescent Medicine 2005; 159(7):626-631.

⁴⁷ Satia JA, Galanko JA, Siega-Riz AM, Eating at fast food restaurants is associated with dietary intake, demographic, psychosocial and behavioural and behavioral factors among African Americans in North Carolina. Public Health Nutrition: 7(8), 1089-1096.

⁴⁸ Guthrie JF. et al. Role of Food Prepared Away from Home in the American Diet, 1977-78 Versus 1994-96: Changes and Consequences. J Nutr Educ Behav 2002; 34(3):140-150.

⁴⁹ Binkley, UK, Eales J, Jekanowski M, The relation between dietary change and rising US obesity. International Journal of Obesity (2000) 24, 1032-1039

⁵⁰ Bowman S, Vinyard B. Fast food consumption of US adults: impact on energy and nutrient intakes and overweight status. Journal of the American College of Nutrition 2004; 23(2):163-168

⁵¹ Duerksen SC, Elder JP, Arredondo EM, Ayala GX, Slymen DJ, Campbell NR, Baquero B. Family restaurant choices are associated with child and adult overweight status in Mexican-American families. Journal of the American Dietetic Association 2007; 107(5): 849-853.

⁵² French SA, Story M, Neumark-Sztainer D, Fulkerson JA & Hannan P. Fast food restaurant use among adolescents: associations with nutrient intake, food choices and behavioral and psychosocial variables. International Journal of Obesity, 2001; 25: 1823-33.

⁵³ Pereira MA, Kartashov AI, Ebberling CB, VanHorn L, Slattery ML, Jacobs DR & Ludwig DS. Fast-food habits, weight gain, and insulin resistance (the Cardia study): 15-year prospective analysis. Lancet 2005; 365:36-42

10,000 adolescents, more days of fast food consumption at baseline predicted increases in BMI at five-year follow-up.⁵⁴ Children eat almost twice (1.8 times) as many calories when eating out than when eating at home.⁵⁵ In a cross-sectional study of boys and girls in three age groups, those aged 12-19 years who consumed foods away from home were more likely to have a higher Body Mass Index (BMI) percentile.⁵⁶ The increase in calories related in part to fast food consumption translates into an increase in body weight in both adults and children. 57,58,59,60,61

25. Some studies specifically examine other settings and support the conclusion that sit-down chains, and not only fast food chains, serve food associated with increased caloric intake and weight gain. One study compared food selections made by adolescents who were asked to order a dinner meal from both sit-down chain restaurants and fast food

⁵⁴ Niemeier H, Raynor H, Lloyd-Richardson E, Rogers M, Wing R. Fast food consumption and breakfast skipping: predictors of weight gain from adolescence to adulthood in a nationally representative sample. Journal of Adolescent Health 2006; 39:842-849.

⁵⁵ Zoumas-Morse C, Rock C, Sobo E, Neuhouser M. Children's patterns of macronutrient intake and associations with restaurants and home eating. Journal of the American Dietetic Association 2001; 101(8):923-925.

⁵⁶ Huang TT, Howarth NC, Lin BH, Roberts SB & McCrory MA. Energy intake and meal portions: associations with BMI percentile in US Children. Obesity Research 2004; 12 (11): 1875-1885

⁵⁷ Duffey KJ, Gordon-Larsen P, Jacobs DR, Williams OD & Popkin BM. Differential associations of fast food and restaurant food consumption with 3-y change in body mass index: the Coronary Artery Risk Development in Young Adults Study. American Journal of Clinical Nutrition 2007; 85:201-208.

⁵⁸ French SA, Harnack L, Jeffery RW. Fast food restaurant use among women in the Pound of Prevention study: dietary, behavioral and demographic correlates. International Journal of Obesity 2000. 24:1353-1359.

⁵⁹ Niemeier H. Raynor H, Lloyd-Richardson E, Rogers M, Wing R. Fast food consumption and breakfast skipping: predictors of weight gain from adolescence to adulthood in a nationally representative sample. Journal of Adolescent Health 2006; 39:842-849.

⁶⁰ Pereira MA, Kartashov AI, Ebberling CB, VanHorn L, Slattery ML, Jacobs DR & Ludwig DS. Fastfood habits, weight gain, and insulin resistance (the Cardia study): 15-year prospective analysis. Lancet 2005; 365:36-42.

⁶¹ Thompson OM, Ballew C, Resnicow K, Must A, Bandini LG, Cyr H, Dietz WH. Food purchased away from home as a predictor of change in BMI z-score among girls. International Journal of Obesity 2004; 28:282-289.

restaurants. Meals selected at Chili's, Denny's and Outback Steakhouse had even higher calorie content than at comparison restaurants McDonald's and Taco Bell.⁶²

People consistently underestimate the number of calories consumed

26. Consumers consistently underestimate the calorie content of food items and overestimate the healthfulness of restaurant items.⁶³ Recent studies found that 9 out of 10 people underestimated the calorie content of less-healthy items, and that they did so by an average of more than 600 calories (almost 50% less than the actual calorie content).⁶⁴

27. Even experienced nutrition professionals have difficulty accurately estimating the calorie content of restaurant food. In one study, while these professionals could accurately describe the calories in a cup of milk, they generally underestimated calories in restaurant food by 200 to 600 calories. For example, dietitians estimated on average that a typical diner hamburger with onion rings meal had 865 calories when it actually had 1,550. If not even experienced professionals in the field of nutrition are able to accurately estimate the calorie content of restaurant foods, consumers are even less likely to do so. 65

28. The differences in calories are not always intuitively obvious, and a far lower calorie option is often available within a group of similar products. For example, calories in cheeseburgers at Burger King vary more than three-fold, not even counting the fries and drinks:

Cheeseburger Whopper Junior with cheese

330 calories 410 calories

⁶² Yamamoto JA, Yamamoto JB, Yamamoto BE, Yamamoto LG. Adolescent calorie/fat menu ordering at fast food restaurants compared to other restaurants. Hawaii Med J. 2006 Aug;65(8):231-6

⁶³Burton S, Creyer EH. What consumers don't know can hurt them: Consumer evaluations and disease risk perceptions of restaurant menu items. The Journal of Consumer Affairs. 2004; 38(1):121-145.

⁶⁴Burton S, Creyer EH. et al. Attacking the obesity epidemic: the potential health benefits of providing nutrition information in restaurants. Am J Public Health. 2006; 96(9):1669-1675.

⁶⁵J. Backstrand, et al., Fat Chance (Washington, DC: Center for Science in the Public Interest, 1997).

Double Whopper with cheese	
Triple Whopper with cheese	

990 calories 1,230 calories

A consumer ordering a salad at Burger King with the goal of eating food with fewer calories might be startled to learn that dressing can have more calories than the salad; and the calories can vary two-fold – from 300 to 670 – not counting the croutons:

BK Tendergrill Chicken Garden Salad	240 calories
BK Tendercrisp Chicken Garden salad	400 calories
Ken's Fat free Ranch Dressing	60 calories
Kens' Honey Mustard Dressing	270 calories

Or if choosing a dessert at McDonald's, that calories can vary more than ten-fold:

McDonald's shakes	420-1160 calories
McDonald's hot fudge sundae	330 calories
Fruit and yogurt parfait with granola	160 calories
Vanilla low fat ice cream cone	150 calories
Apple dippers w/ low fat caramel dip	105 calories

Both common sense and published scientific evidence indicate that making this information readily available at the point of purchase will influence many consumers to make lower-calorie choices.⁶⁶ Attached hereto as Exhibit 8 is Burton, et al, "Attacking the Obesity Epidemic: The Potential Health Benefits of Providing Nutrition Information in Restaurants."

Leading scientific authorities recommend that calorie information be readily available in restaurants, including at point of purchase

29. The final report of the FDA-commissioned Keystone Forum on Away-From-Home Foods recommends that: "Away-from-home food establishments should provide consumers with calorie information in a standard format that is easily accessible and easy to use." This was the first recommendation in Chapter 4 of the report, "Providing

⁶⁶Burton S, Creyer EH, Kees J, Huggins K. Attacking the obesity epidemic: the potential health benefits of providing nutrition information in restaurants. Am J Public Health. 2006; 96:1669-1675.

Consumers with Nutrition Information." Putting calorie information on menus and menu boards is consistent with this recommendation. As the report noted when providing operational tips for accomplishing its recommendation:

Document 33

Information should be provided in a manner that is easy for consumers to see and use as part of their purchasing and eating decisions. Consumer might view such information, for example, when standing at a counter, while reviewing a menu board, in a car when reading a drive-through menu, or when sitting down at a table reviewing a menu, a table tent, or others means of providing information."⁶⁷

Attached hereto as Exhibit 9 is the Keystone Forum Report. 68 Plaintiff's Memorandum cites other parts of the report, such as the desirability of further research, but not this key recommendation.

30. In addition to the Keystone Forum report, some of the nation's leading authorities on health, including the Institute of Medicine, the Surgeon General, and the President's Cancer Panel, have recommended that nutrition information be available in restaurant settings, to address the nation's obesity epidemic, including at the point of purchase. The Institute of Medicine recommended that: "Fast-food and full-service restaurants should expand healthier meal, food, and beverage food options (including children's meals) and provide calorie content and general nutrition information at point of

⁶⁷The Keystone Center. The Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity. Final Report. May 2006. Washington, D.C. [Report commissioned by the U.S. Food and Drug Administration.] URL: http://www.keystone.org/spp/documents/Forum Report FINAL 5-30-06.pdf.

⁶⁸ Debra Demuth, the Global Director of Nutrition for McDonald's states in her declaration that "The actual recommendation in the report is that "home food-establishments should provide consumers with calorie information in a standard format that is accessible and easy to use. This recommendation emphasizes accessibility and ease of use - calorie content next to price on menu boards may not be the solution." The last sentence, italicized above, is presented by Dumuth as if it were part of the recommendation. Yet, it does not appear in the Keystone Report and presumably represents instead an editorial comment by Demuth.

The Surgeon General of the United States has called for industry to purchase."69 "Increase availability of nutrition information for foods eaten and prepared away from home."⁷⁰ The 2006-2007 report of the President's Cancer Panel, in light of the increasing contribution of obesity to cancer, recommends: "Make nutrition information on restaurant foods readily available on menus and understandable to consumers." Clearly, the Board of Health is taking a position recommended by a wide range of public health, nutrition, and medical experts, in concluding that the best available scientific evidence supports the provision of calorie information at point of purchase.

Consumers want calorie information and use it to make more informed choices

31. Since 1994, the federal Nutrition Labeling and Education Act (NLEA) has made nutrition information available to consumers on packaged foods purchased in retail stores. This information is widely used, with three quarters of American adults reporting that they examine food labels, 72 the calorie section is the most frequently consulted part of the Nutrition Facts panel on packaged foods, with 73% of consumers reporting that they look at calorie content.⁷³ Nearly half (48%) of those who consult the nutrition

⁶⁹Institute of Medicine of the National Academies. Industry can play a role in preventing childhood obesity. Fact Sheet 2004. Drawn from Preventing Childhood Obesity, Health in the Balance 2005. Accessed at www.iom.edu on February 2, 2008.

⁷⁰ U.S. Department of Health and Human Services. The Surgeon General's call to action to prevent and decrease overweight and obesity. Rockville, MD: U.S. Department of Health and Human Services, Public Health Service, Office of the Surgeon General; [2001].

⁷¹ President's Cancer Panel. Promoting Healthy Lifestyles. Policy, Program and Personal and Recommendations for Reducing Cancer Risk. 2006-2007 Annual Report. U. S. Department of Health, National Institutes of Health, National Cancer Institute. Bethesda, Maryland, 2007.

⁷² US Department of Health and Human Services (US DHHS), Centers for Disease Control and Prevention, National Center for Health Statistics. Healthy People 2000 Final Review. 2001.

⁷³ International Food Information Council (IFIC) Foundation. Food & Health Survey: Consumer Attitudes Toward Food, Nutrition & Health. Washington, DC: 2007.

information on packaged foods report changing their food purchasing habits as a result of reviewing this information.⁷⁴

32. Similarly, consumers are interested in knowing the calorie content of restaurant foods and will use it to make more informed choices. Six nationally representative polls have found that 62% to 87% of Americans support requiring restaurants to list nutrition information.^{75,76} In studies where calorie information is provided, consumers choose high-calorie items 24% to 37% less often. 77,78 A DOHMH exit interview and receipt study conducted in May and June of last year demonstrated that patrons of Subway who saw calorie information at the point of purchase chose items with fewer calories. At the time of the study, Subway – NYC's second-largest chain, with 315 restaurants - posted nutritional information for some of its products on a sticker placed on a display case near the cash register - a manner far less prominent than that mandated by §81.50. Nevertheless, among the 1,816 Subway patrons sampled at 47 randomly selected Subway locations, nearly one third (30.8%) reported seeing the calorie information (preliminary data). Further, patrons who saw calorie information purchased items containing 48 fewer calories than patrons who did not see it. 79 Furthermore, patrons who acknowledged that calorie information had affected their selection were

⁷⁴ Levy AS. Derby BM. The Impact of NLEA on Consumers: Recent Findings from FDA's Food Label and Nutrition Tracking System. Washington DC: Center for Food Safety and Applied Nutrition. Food and Drug Administration, 1996.

⁷⁵ Center for Science in the Public Interest. Anyone's Guess: The need for nutrition labeling at fast-food and other chain restaurants. Washington, DC: Center for Science in the Public Interest, 2003.

⁷⁶ Harvard Forums on Health. Obesity as a Public Health Issue: A Look at Solutions. National Poll by Lake, Snell, Perry & Associates. June 2003.

⁷⁷ Burton S, Creyer EH, Kees J, Huggins K. Attacking the obesity epidemic: the potential health benefits of providing nutrition information in restaurants. Am J Public Health. 2006; 96:1669-1675.

⁸Once again, the Demuth declaration does not accurately reflect an authority it cites. Describing the Burton study, she states, "Purchase intent for the more-healthy items was increased only when both calorie plus nutrient information were provided." In actuality, the authors concluded that while calorie information with additional nutritional information affected more choices, calorie information alone had a significant effect on certain consumer purchase intentions.

⁷⁹Department of Health and Mental Hygiene, unpublished data 2007.

Page 24 of 48

correct - they chose items with 92 fewer calories, a statistically significant finding. That their self-report of use of calorie information matched the data from their receipts that documented lower-calorie choices is consistent with findings that when consumers say they will change choices based on calorie information, they often actually do so. These findings strengthen earlier evidence on changes in purchase intent when people see calorie information by actually documenting changes in what people buy after seeing calorie information. Further description of this study, its analysis and assumptions used to project its impact are given in a declaration by Dr. Mary T. Bassett, attached hereto as Exhibit 10.

33. Based on the best estimates, if, after §81.50 becomes effective, the reduction in calories at other chain restaurants is similar to what occurred at Subway, over the next five years at least 150,000 fewer New Yorkers will be obese, resulting in at least 30,000 fewer cases of diabetes, and many other health benefits. 81

34. The Plaintiff questions the usefulness of calorie information if consumers are unaware of their recommended daily calorie intake. Such knowledge, however, is not essential for calorie posting to be effective. As noted in the Keystone Forum report: "The data collected since the NLEA was implemented in 1994 suggest that people tend to use food label information to compare "like" products, rather than to make selections across product lines."82 Similarly, calorie counts provided in restaurants allow consumers to

⁸⁰ Burton S, Creyer EH, Kees J, Huggins K. Attacking the obesity epidemic: the potential health benefits of providing nutrition information in restaurants. Am J Public Health. 2006; 96:1669-1675.

In his declaration, Dr. David B. Allison critiques that estimate. Technical responses to the issues he raises are attached in the declaration of Dr. Mary Bassett.

⁸² The Keystone Center. The Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity. Final Report. May 2006. Washington, D.C. [Report commissioned by the U.S. Food and Drug Administration.] URL: http://www.keystone.org/spp/documents/Forum_Report_FINAL_5-30-06.pdf.

compare meal options, facilitating better selections irrespective of whether they know their daily recommended calorie intake. For example, a consumer will be able to choose between a small portion of McDonalds fries knowing that it has 250 calories versus a large portion at fries at 570 calories, between its Deluxe Breakfast with syrup at 1,410 calories instead of the Big Breakfast with a regular sized biscuit at 720 calories, or between a large Coke at 310 calories versus a small one for 150 calories or a diet Coke for <1 calorie.

35. Increased portion sizes are an important driver of increased caloric intake. Calorie increases with larger portions are not intuitive or obvious from the price differentials, and calorie information will be particularly important to highlight these increases. An 11% price differential can be accompanied by a 50% differential in calories. For example, going from a McDonald's \$1.79 medium fries with 380 calories to a \$1.99 large fries with 570 calories is an 11% price increase but a 50% calorie increase. Ordering a healthy-sounding Starbuck's Green Tea Frappuccino in its large version rather that the \$3.75 small version is 32% more expensive but results in a 76% increase in calories for a total of 650 calories.

Making calorie information readily accessible to diners will likely result in the development of healthier menu offerings

36. We anticipate that in addition to informing consumers, calorie posting will motivate the food service industry to improve its menu offerings. According to the FDA-sponsored Keystone Forum, "A key benefit of mandatory nutrition labeling on packaged foods has been the reformulation of existing products and the introduction of new, nutritionally improved products. Between 1991 (before the implementation of the NLEA)

and 1995 (after implementation) the number of fat-modified cheeses has tripled, and market share for fat-modified cookies increased from zero percent of the market to 15%. In a similar fashion, nutrition labeling on menus and menu boards may spur nutritional improvements in restaurant foods."83

Current nutrition information practices are woefully inadequate

- 37. The current nutrition information practices of chain restaurants do not effectively transmit calorie information to consumers. Some chains fail to provide any nutrition information to consumers. While plaintiff has submitted declarations from some that do, the methods they utilize off-site are accessed by only a minuscule proportion of their customers. For instance, according to the declaration of Debra DeMuth, Director of Global Nutrition for McDonald's, McDonald's has over 50 million patrons per day, amounting to 18.3 billion visits per year, but receives only 736,000 annual "hits" on their nutrition information website - presumably including search engine redirects and other spurious hits. Even if we attributed all website hits to customers, this would represent a rate of 0.004% nutrition information hits per meal (or one hit for every 25,000 meals). If all methods described by DeMuth for capturing consumer use of nutrition information, or even simply nutrition advice (736,000 website visits, a projected 48,000 annual calls to the toll free hotline), use of these sources remains minuscule compared to the volume of meals served.
- 38. Similarly, in Burger King's Fiscal 2007 Annual report, it is noted that "Worldwide 11 million guests a day visit a BURGER KING restaurant." In Haugen's

⁸³ The Keystone Center. The Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity. Final Report. May 2006. Washington, D.C. [Report commissioned by the U.S. Food and Drug Administration.] URL: http://www.keystone.org/spp/documents/Forum Report FINAL 5-30-06.pdf.

Page 27 of 48

declaration, she notes that the Burger King website receives an average of 71,000 visits a month, while its interactive "Build a Meal" site receives approximately 42,000 visits each month. Further, the linked "Healthy Dining Finder" has received, since March 2007, about 60,000 hits. Even when considering all of these as unique visits by customers, certainly an overestimate, there are perhaps 1.42 million electronic inquiries for nutritional information. This is certainly a large number, but when compared to Burger King's some 4 billion customer visits each year, it translates to 0.0355% of meals (or one in 3,000) served for which nutritional information has been obtained electronically.

39. Burger King cites its sponsorship of "Healthy Dining Finder" as evidence of its commitment to consumer information. It is of interest that this site, supported by some chains, recommends maximum levels of caloric consumption well below the means found during lunchtime at most chains, and 176 calories below the lunchtime mean for Burger King (See Table 2):

The Food and Drug Administration (FDA) uses 2,000 calories per day as a reference level for nutrition labeling. Healthy Dining's upper limit of 750 calories for one meal [emphasis added] represents about 37% of total calories for the day reasonable, because a restaurant meal is generally the largest of the day. Most of the menu items featured on this site have significantly fewer than 750 calories. 84

40. Despite the initiatives by McDonald's described in the DeMuth Declaration, calorie information is invisible to the overwhelming majority of consumers who stand on line each day and order items from its menu boards. As described in the declarations submitted by plaintiff, chain restaurants do not typically display nutritional information where and when consumers make their choices and purchases. Such information is

⁸⁴ www.healthydiningfinder.com Accessed February 6, 2008.

typically displayed only where it is hard to find, difficult to read, or accessible only after a purchase is made. Thus, the provided information has little or no impact on choice.

Fewer than one in ten consumers see currently furnished on-site information

- 41. The existing activities for onsite provision of nutrition information described in the declarations of Demuth (McDonald's), LeClair and Fitzgerald (Dunkin' Brands), Muñoz and Haugen (Burger King Corporation), Liewen (Yum! Brands, Inc.) and Roach (Domino's), using methods that they claim to be more comprehensive than the requirements of §81.50, are also not effective in transmitting this information to consumers.
- 42. The Department conducted a large exit interview survey of 11,865 diners at a random sample of 274 of restaurants that would have been covered by the previous version of §81.50 in May and June of last year. With the exception of Subway, less than 5% of chain restaurant consumers reported seeing calorie information. Even at the chain restaurants (McDonald's, Dunkin' Donuts, Burger King, and Yum Brands locations) that have submitted declarations in support of plaintiffs' motion, and whose declarations claim that they provide extensive nutrition information to their customers, fewer than 5% of customers saw any calorie information. See Table 1, below.
- 43. Only at Subway, which was already posting some nutritional information at the time of our survey, did a substantial proportion 31% of consumers report seeing calorie information. When chain restaurants are required to post calories even more prominently, as required by Health Code §81.50, consumers will be even more likely to see the information when they are making purchases, and to make healthier choices.

Table 1. Percent of consumers who see calorie information at New York City establishments covered under Health Code §81.50 ("Calorie Labeling"), with their existing information practices in May-June 2007

Page 29 of 48

Brand # of Sites		# of Customers Interviewed	% of Customers who Reported Seeing Calorie Information in the Restaurant		
Dominos	10	57	0.0%		
Papa Johns	5	222	0.0%		
Popeyes	7	512	0.6%		
Dunkin Donuts	70	2,756	1.3%		
Starbucks	37	1,285	2.7%		
Au Bon Pain	2	166	3.7%		
Burger King	20	1,033	3.8%		
Yum Brand	21	861	4.6%		
McDonald's	45	2,593	4.7%		
Wendy's	11	474	6.9%		
Subway	48	1,906	31.3%		

44. The key difference between current practices and the provisions of §81.50 is that calorie information will be seen by most consumers under §81.50 while it is seen by fewer than 5% of consumers (excluding Subway) using present methods. Furthermore, it will be seen at the point of purchase, before consumers select their order.

45. Provision of calorie information in restaurants can have an impact even if not all patrons make use of the information. The DeMuth declaration cites Krukowski's report⁸⁵ that 44-57% of students in a study said that they were not likely to use food caloric information as an argument against calorie posting. Yet, conversely 43-56% of patrons in that same study stated that they would use nutrition information if it were available, suggesting that calorie posting will have a substantial effect on public health. National estimates suggest that affecting energy balance by even 100 calories per day could alter the trajectory of the average weight gain that is driving the obesity epidemic. 86 Even the National Restaurant Association accepts this, stating "Research shows that

⁸⁵ Krukowski RA, Harvey-Berino J, Kolodinsky J, Narsana RT, Desisto TP. Consumers may not use or understand calorie labeling in restaurants. J Am Diet Assoc 2006; 106(6):917-20.

³⁶ Hill JO, Wyatt HR, Reed GW, Peters JC. Obesity and the environment: where do we go from here? Science 2003; 299(5608):853-5.

affecting energy balance by 100 calories per day could prevent weight gain in most of the population."87

Chains are the most appropriate focus for calorie posting requirements

46. Chain restaurants represent an appropriate focus for regulation for several reasons. Because chains serve a disproportionately large number of meals in NYC, the public health impact of providing this information will be great. Second, as outlined above, the vast majority of chain restaurants typically serve food that is clearly associated excess caloric intake and with obesity. In addition, children, an especially vulnerable segment of the population, are targeted by chain restaurant marketing campaigns.

The disproportionate market share of major restaurant chains in NYC will increase the health impact of calorie posting

47. Of the 23,000 FSEs issued permits by the Department, the Department estimates that at least 2,618 are chain restaurants that will be required by Health Code §81.50 to post calorie information on their menus and menu boards, i.e. if they are one of a group of fifteen or more food service establishments doing business nationally under the same name, and offering for sale substantially the same menu items. restaurants account for a much larger proportion of restaurant meals than suggested by their number (i.e., far more than 10% of meals). 88 Data from The NPD Group, a major market research company, indicate that, in 2007, major chain restaurants in the NYC metropolitan area accounted for more than one third of all restaurant traffic $-34.7\%^{89}$ – more than three-fold their representation among food service establishments overall. In

⁸⁷ Garren DM, Gay J. Comment; Notice of Intention to Repeal and Reenact 81.50 to Article 81 of the New York City Health Code; Mandatory calorie Statements. National Restaurant Association. November 27,

⁸⁸ The NPD Group, presentation to the Keystone Forum on Away-from-Home Foods, April 26, 2005.

⁸⁹ The NPD Group / CREST (marketing research data)

fact, we estimate that this regulation has the potential to affect consumer choices involving at least 145 million meals in New York City per year, and possibly as many as 500 million or more.⁹⁰ Even in the highly unlikely event that the calorie labeling regulation has little or no impact on consumer food choices, it is likely to increase the number of lower-calorie menu items, as did the NLEA, and reduce the number of highercalorie offerings these facilities provide.

Patrons of chains restaurants purchase meals with elevated caloric content

48. While the plaintiffs Memorandum of Law noted "overemphasis on any one nutrient such as calories can interfere with consumers obtaining a healthy, varied diet", our survey data show that many of their patrons purchased food that exceeded a reasonable share of recommended daily calorie intake. More than half of consumers (54%) exceeded the 750 calorie upper limit for one meal recommended on the restaurant industry's Healthy Dining Finder. One third of consumers at the restaurants surveyed purchased more than 1,000 calories, and 15% purchased single meals containing more than 1,250 calories. The declaration of Valerie Roach expounds on the efforts of Domino's to provide nutrition information to its customers. Yet none of the surveyed Domino's customers reported seeing the nutrition information purportedly available. The mean calorie content of a meal ordered at Domino's was 1309, 89% of their customers exceeded 750 calories, and more than half of Domino's customers purchased more than 1,000 calories.

49. While the Haugen Declaration for Burger King proudly notes its participation in the Healthy Dining Finder website, the average calorie content of purchases at Burger

 90 Department of Health and Mental Hygiene calculated this value using 10%-34% of annual estimated restaurant meals.

King's surveyed New York City restaurants exceeded the 750 calories per meal recommended on the site by over 175 calories and fully 62% of Burger King customers purchased more than 750 calories.

Table 2. Calorie content of purchases for individual lunch hour customers at selected New York City chain restaurants, with their pre-existing information practices in May-June 2007*, **

Chain	# of sites	# of Customers Interviewed	Mean calories purchase d	% Purchasing over 750 calories	% Purchasing over 1,000 calories	% Purchasing over 1,250 calories
Domino's	9	44	1309	81.8	52.3	36.4
KFC/TB	1	42	938	71.4	42.9	21.4
PH/KFC	1	49	956	71.4	46.9	20.4
Popeye's	5	302	948	69.5	51.7	19.2
Taco Bell	3	96	900	66.7	41.7	17.7
KFC	9	347	917	66.3	43.8	17.0
Pop/BK	3	166	900	63.3	45.8	19.9
Burger King	19	969	926	62.0	43.8	22.6
Wendys	11	434	858	62.0	33.2	11.8
McDonald's	45	2454	829	54.7	37.5	15.0
TB/PH	4	198	788	51.0	22.7	12.6
Pizza Hut	3	22	1018	50.0	36.4	31.8
Subway	47	1830	749	46.1	21.3	9.4
Au Bon Pain	2	159	555	25.2	5.7	1.9
Papa John's	5	206	623	21.4	12.1	8.7
Total	167	7318	827	54.1	33.5	14.5

^{*} Preliminary data

Targeting children: marketing practices by chain restaurants

50. Many of the chain restaurants that will be affected by the calorie labeling requirement make extensive use of advertising to promote the appeal and wholesome image of their products, particularly to vulnerable groups such as children. The major chains use marketing strategies directly aimed at children to establish a preference for

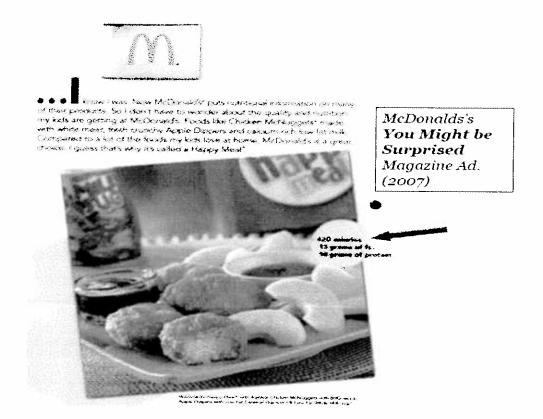
Chains with more than one name were co-located sites

their fast food brand, 91 and children who view such television advertisements are about 50% more likely to eat fast food. 92 Such advertising does not contain any information about caloric content or the risk of obesity in those consuming fast food regularly, and many such advertisements may inaccurately imply that fast food is wholesome, healthy food. Ads typically feature slender, healthy-looking children and parents. The ad below from McDonalds clearly implies that this is good place to obtain a meal for a child where parents "don't have to worry about the quality or nutrition." However, this ad proved deceptive. When my staff ordered a standard children's chicken nugget Happy Meal at McDonalds on February 6, 2008, no substitutions were offered at the counter and the purchased meal consisted of 6 chicken nuggets, a small order of French fries and a regular Coke. Using McDonald's nutritional data posted on their website, this meal had 610 calories – 45% more calories than the advertised meal with low-fat milk and apple slices.

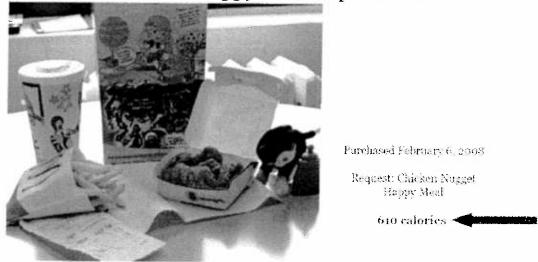
Case 1:08-cv-01000-RJH

⁹¹ Connor, SM. Food-related advertising on preschool television: building brand recognition in young viewers. Pediatrics. 118(4):1478-85, 2006

⁹² Taveras EM, Sandora TJ, Shíh, M-C, Ross-Degnan D, Goldmann DA, Gillman M W. The association of television and video viewing with fast food intake by preschool-age children. Obesity, 14(11):2034-41, 2006 Nov



The Actual Default Happy Meal as purchased 2.6.2008



Top: P. 3 McDonalds "You might be surprised to learn who thinks about your child's nutrition as much as you do" ad, 2007. Bottom: Actual "Default" Chicken Nuggets meal as purchased NYC Feb. 6, 2008.

51. Researchers at Robert Wood Johnson Foundation's national research program Bridging the Gap found that fast-food advertisements make up the largest category of all food related advertisements seen by teens. 93 "Clearly our kids are getting bombarded with poor nutritional messages every day," said Risa Lavizzo-Mourey, M.D., M.B.A., president and CEO of the Robert Wood Johnson Foundation. 94 An NIH-supported study looked television fast-food restaurant advertising seen by children and estimated that these advertisements were responsible for 18% of overweight in children ages 3-11 and 14% in adolescents.95 Given the epidemic of childhood obesity, calorie posting is an important tool to help parents offset the effects of fast-food advertising on their children.

52. The argument that requiring posting by some and not all restaurants will create a competitive disadvantage for affected restaurants is purely speculative, as is the allegation that these restaurants will lose business. In fact, it is entirely plausible that consumers, who are increasingly choosing foods based on nutritional value or perceptions of healthfulness, will prefer purchasing at restaurants where calorie information is available. Similar dire predictions were raised when New York City passed the Smoke-Free Air Act ("SFAA"), effective in March 2003, to eliminate tobacco smoking from virtually all indoor workplaces, including all restaurants and bars. The City's limitations on public smoking, coupled with other measures, have reduced the numbers and percentages of people who currently smoke in the City. NYC adult smoking prevalence declined 19% between 2002 and 2006 (from 21.5% to 17.5%), resulting in about 240,000

93 Powell, LM, Szczypka G, Chaloupka, FJ, Braunschweig CL. Nutritional content of television food advertisements seen by children and adolescents in the United States. Pediatrics 120:576-583, 2007.

⁹⁴ Robert Wood Johnson Foundation. New Study Confirms Vast Majority of Ads Seen by Kids Promote Foods High in Sugar, Fat or Sodium. Sep 4, 2007 - Chicago, Ill. Accessed February 6, 2008 at http://www.rwjf.org/newsroom/newsreleasesdetail.jsp?productid=21922

⁹⁵ Chou SY, Rashad I, Grossman M. Fast Food Advertising on television and its influence on childhood obesity. R01 DK54826 from the National Institute of Diabetes and Digestive and Kidney Diseases Report. December 2006.

- 53. Furthermore, dire predictions made about the effects of smoke-free legislation on business failed to materialize. From April 1, 2003 through January 31, 2004, business tax receipts in restaurants and bars increased 8.7%; from March to December 2003, and employment in restaurants and bars increased by 10,600 jobs (about 2,800 seasonally adjusted jobs). 97
- 54. Similar to predictions around the Smoke-Free Air Act, we believe that these dire predictions will prove baseless. The proposal to require calorie labeling had widespread social support during an active public comment period. It is equally likely that the availability of calorie information to consumers may come to be seen as a competitive advantage by plaintiff and its patrons.
- 55. In contrast to the declarations by some of the restaurants that will be covered by §81.50 (Mr.Fitzgerald, Mr. Liewen and Mr. Muñoz) predicting revenue loss, consumer confusion and delays on lines, Subway Restaurants, the second largest chain in the City, where calorie posting was implemented in response to the previous version of §81.50, and maintained voluntarily, reported no such difficulties. As part of a Centers for Disease Control and Prevention educational webcast, John Musco, Development Agent for Subway restaurant's Greater New York Region, said this about the calorie posting

⁹⁶ Decline in Smoking Prevalence in new York City 2002-2006. Morbidity and Mortality Weekly Reports. June 22, 2007 / Vol. 56 / No. 24

⁹⁷ NYC Department of Finance, NYC Department of Health & Mental Hygiene, NYC Department of Small Business Services, NYC Economic Development Corporation. The state of smoke-free New York City: A one-year review. 2004.

measure: "We've seen no negative feedback, no loss of sales in our stores because of it. It's been positive." 98

Subway Menu Boards in Place in Manhattan on July 2, 2007

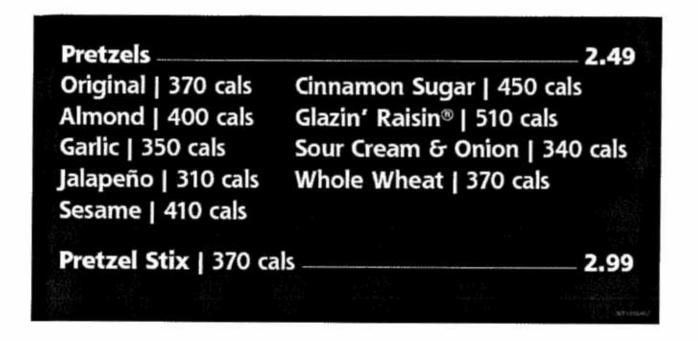


Auntie Anne's Menu Board in Place in New York City

37

⁹⁸ Centers for Disease Control and Prevention and University of North Carolina at Chapel Hill School of Public Health. Cutting-Edge Legal Preparedness for Chronic Disease Prevention. Public Health Grand Rounds [webcast]. November 29, 2007.

http://www.publichealthgrandrounds.unc.edu/legal/webcast hi.htm



Proposal requires a disclosure, it does not force a message

56. In the Memorandum of Law the Plaintiff argues that the governments point of view is that "patrons *must* consider the caloric content of food when ordering in a restaurant, and that calories are the only nutritional criterion that patrons need to consider." The reenacted §81.50 requires restaurants only to disclose a fact where customers can see it when making purchases. Calorie posting would not force anyone to take anything into consideration, any more than having labels on clothing (which are mandatory) forces you to buy cotton rather than polyester, or access to Nutrition Facts Panel forces you to buy tofu. It simply requires that consumers have ready access to calorie information when making a choice. Nor does §81.50 in any way imply that calories are the only important nutritional criterion. It simply establishes a minimum requirement for disclosure of the information of the greatest public health importance in the setting of an obesity epidemic. Nor is it correct that a focus on calories is one

nutritional view. Calories are a measurement of the objectively measured physical property of the energy content of food. The number of calories one consumes, relative to calories expended, translates directly into weight gain or loss.

Mandating calorie listing on menu boards is a narrowly tailored requirement necessary to effectively communicate with consumers

- 57. In contrast to the virtual invisibility of nutritional information in virtually all chains with the exception of Subway, the menu board is an effective means of providing information. Several of the declarations submitted by plaintiff describe how effectively menu boards can communicate information that restaurants wish to share with their patrons. "Menu boards are... the primary way most industry members communicate information about products" (Fitzgerald, Dunkin' Brands); "It is the most important way we communicate with our customers in the store about the products we offer and their price; it is what our customers look at and it is what stimulates their decision to buy" (Muñoz, Burger King); "most important mode of communication inside the store" (Smoot, McDonald's). These statements confirm the Department's position that posting calories on menu boards is essential to inform consumers about calories and overcome the failure of current practices to transmit the information to more than a small fraction of customers.
- 58. Dunkin' Donuts submitted a sample menu board under the previous rule in an attempt to demonstrate that calorie information would not fit along with price information. From that sample, the Department's director of graphics produced a replica of the menu board with comparable fonts and layout to demonstrate that calories could be listed easily and visibly, as shown in the illustrations in Mr. Krueger's declaration. These

modifications provide clear evidence that calorie listings required by the regulations are feasible to implement with basic graphic design techniques.

The reenactment provides more flexibility

- 59. The reenacted rule incorporates all of the alternative design elements that were presented to the Department in anticipation of the earlier regulation and met the standard of presenting calorie information with equal prominence to the information menu items and their prices. It adds as much flexibility as possible while still assuring adequate prominence of the information. Provisions that are more flexible than the previously enacted rule include: a) the use of separate stanchions with calorie information for drive-through windows; b) greater flexibility in the size of the calorie information in relation to menu item price and name calorie information must be listed clearly and conspicuously and as large as either the menu item or price; c) there is added flexibility in placement of the information, which must only be adjacent or in close proximity to the menu item in order to be associated with it.
- 60. Subway put the new menus and boards into place without alternative designs. Their work demonstrates clearly that calorie posting can be provided while still offering clear, attractive and uncluttered menu boards.

Customization, fresh foods and calorie posting are compatible

61. Liewen of Yum! Brands, Muñoz of Burger King, and Roach of Domino's questioned the accuracy of calorie counts in light of customization. While some customization does occur, it is not an argument against calorie posting. Chain restaurants, including those that raised concerns in declarations as noted above, provide calorie information for standardized meals and meal items, without reflecting

customization. Customization often results in small changes in calorie content, particularly when compared to alternative menu item choices. For example, a decision to "hold the pickles" would reduce the calorie count by 0 calories; "hold the onions" by 5 calories. For going the mayonnaise on a Burger King WHOPPER ® Sandwich with cheese would save 160 calories. But calorie savings accomplished by more calorie-conscious customizations are minor compared to the difference between choosing a Burger King fire-grilled hamburger (290 calories) instead of a DOUBLE WHOPPER ® Sandwich (900 calories, a 610 calorie increase), a BKTM Quad Stacker (1,000 calories, a 710 calorie increase), or a TRIPLE WHOPPER® Sandwich with Cheese (at 1,230 calories, a 940 calorie increase). The selection of the standard item is the most important calorie decision made by the patron.

62. Posting calories associated with these meal items does not change the opportunity for customization. Indeed, one important use of calorie posting will be to provide consumers with valuable information they can use, should they wish to do so, to 'customize' their order to reduce calories, for example by substituting salad for French fries or diet soda for regular soda. Establishments can account for individual customization of an item by posting calories for the standard preparation of the item, along with a disclaimer that calorie amounts may differ due to individual customization. Many establishments already provide such disclaimers on their publicly available calorie information. For certain menu items that covers a number of different flavors or varieties, such as "Soda, Small," a range of calories can be provided.

⁹⁹ Pickle & onion calorie values: http://www.bk.com/#menu=3,1,-1 (the build-a-meal section of the burgerking.com website)

Burger King burger calorie values: http://www.bk.com/Nutrition/PDFs/brochure.pdf

63. Contrary to assertions of the Plaintiff, restaurant chains use highly standardized menu items and food preparation and can readily measure or estimate accurate calorie counts. In considering the standardization requirement, Mr. Randolph, from TGI Friday's, states that their food is often cut, measured and prepared by hand by individual cooks in its restaurants, introducing some variation. He also states, "our cooks follow specifications on how to prepare dishes, and they and other employees receive training on how to prepare and present our menu items." Calorie posting under §81.50 applies only to standardized "menu items." If there is no standard formulation for a menu item, then it is not covered. This, however, does not mean that any deviation in processing or preparation makes a menu item non-standardized, or that an entrée has to be exactly alike each time it is served. The Oxford English dictionary defines "standardized" as meaning "cause to conform to a standard." Chain restaurants, as evidence by the declaration of Mr. Randolph, employ processes and follow specification to ensure consistency in the preparation of their menu items. For that reason, it is feasible for them to post calories.

The scientific community and the public overwhelmingly support calorie labeling

- 64. Public interest at the time of both proposals was substantial and overwhelmingly favorable. National, state and local organizations that submitted statements supporting calorie posting (either one or both proposals) included:
 - American Medical Association (both)
 - American Diabetes Association (both)
 - American Cancer Society (both)
 - American Heart Association (reenactment)
 - Center for Science in the Public Interest (both)
 - National Hispanic Medical Association

- New York Academy of Medicine
- Institute for Urban Family Health
- Medical Society of the State of New York
- Northern Manhattan Perinatal Partnership
- Citizen's Committee for Children (both)
- Conscious Cooking
- FoodChange
- New York Coalition for Healthy School Lunches
- American Medical Student Association (local)
- Harlem Consumer Education Council
- Empire State Medical Association (New York State Affiliate of the National Medical Association)
- American Society of Hypertension Eastern Regional Chapter
- American College of Cardiology (NYS chapter)
- New York Cardiologic Society
- Chapters 2 and 3 of the New York State American Academy of Pediatrics (both)
- Public Health Association of New York City (PHANYC) (both)
- Baum Forum
- East Harlem Partnership for Diabetes Health and Prevention
- Community Health Care Association of New York State (CHCANYS)
- Community Service Society of New York
- Campaign for Bronx Health
- Citizens Advice Bureau
- Family Cook Production
- For a Better Bronx
- Health People
- Urban Health Plan.
- National Action Against Obesity (reenactment)
- New York Healthy Eating and Physical Activity Alliance (reenactment)
- New York City Nutrition Education Network (NYCNEN) (reenactment)
- New York State Public Health Association (reenactment)

Supportive statements were received from the following universities, medical schools and

local hospitals:

- New York University Department of Nutrition, Food Studies, and Public Health
- New York University Nutrition and Dietetics Program
- New York University School of Medicine
- Columbia University Mailman School of Public Health
- Institute for Human Nutrition, Columbia University (reenactment)
- Columbia University Medical Center

- Columbia University New York Presbyterian
- Harlem Hospital Center
- Linking Food in the Environment (LIFE, Columbia University Teacher's College)
- North General Hospital
- Montefiore Medical Center
- Jacobi Medical Center Family Weight Management Program
- · Mount Sinai School of Medicine
- Tufts University Friedman School of Nutrition Science and Policy
- Yale University Rudd Center for Food Policy and Obesity (both)

Attached hereto as Exhibit 11 are representative comments received by the Board of Health in support of Health Code §81.50 from the American Academy of Pediatrics; Public Health Association of New York City and the New York State Association of Public Health; American Cancer Society, Eastern Division and the American Cancer Society Cancer Action Network; American Medical Association; American Heart Association as well as one comment in opposition from the National Restaurant Association.

Standard of evidence for public policy

65. The Allison declaration raises the question of what should be the standard of evidence for promulgating public policy. The standard for recommending certain biomedical interventions is generally the evidence of benefit from randomized, placebocontrolled clinical trials. The grading system which Allison cites is based on an "A" rating for strong evidence from randomized controlled trials in such settings. While such trials represent one of the strongest forms of scientific evidence, they are rarely available, or even feasible, for public policy interventions. For example, could we realistically or ethically randomize people to smoking or not smoking for decades and observe their cancer rates?

- 66. Had evidence from randomized controlled trials been the requirement for implementation of public health policies, we would have failed to implement many of the major public health triumphs on the past hundred years, including:
 - Chlorination of water
 - Fluoridation of water
 - Elimination of lead-based paint
 - Mandatory installation of automobile safety seat belts
 - Smoke detectors
 - Smoke-free air policies
 - Standards to reduce hazardous conditions in the workplace
- 67. Adherence to a rigid standard of randomized controlled trials for social policy making would have cost millions of lives lost to diarrheal diseases, motor vehicle accidents, fires, and cancer as well as resulting in millions more lead-poisoned and intellectually impaired children. Government has the obligation to create public policy wisely, based on the best available evidence, to protect the public's health, and cannot wait until all scientific questions are answered to act, especially when policies that protect the public's health are likely to carry no or minimal risks. Again citing the FDAsponsored Keystone forum report and the Institute of Medicine:

The need for additional research should not preclude reasonable action. As noted in the Institute of Medicine's 2004 report, Preventing Childhood Obesity: Health in the Balance"[t]he obesity epidemic is a serious public health problem that calls for immediate action to reduce its prevalence as well as its health and social consequences. Therefore...actions should be based on the best available evidence—as opposed to waiting for the best possible evidence." With regard to this last consideration, the best available evidence for obesity prevention and control is grounded in a solid, well-documented knowledge base regarding energy balance. Keystone Forum participants believe that

what is needed now is reasonable guidance and action to help make healthy food choices easier for individuals and families. ¹⁰¹

- 68. The Allison declaration also references Seymour et al, 2004¹⁰² among others. Seymour makes clear that not only randomized clinical trials, but a variety of forms of evaluation of effectiveness of nutrition policies are relevant, many of which can only be performed post-implementation: "...policy interventions can be more difficult to evaluate than environmental interventions which may account for the lack of such studies in the literature... The impact of this policy change may not come only from individual awareness, knowledge and behavior change but may also come from changes to the foods served by the restaurant so the nutritional content of menu items pre- and post-intervention should be compared."
- 69. In the DeMuth Declaration, McDonald's argues that "implementing an environmental nutrition intervention point of purchase that has not been carefully evaluated through research poses risks to the consumer and does not reflect sound public health practices." The City and many leading scientists, as shown in their declarations and in comments during the rule's public-comment period, disagree with this statement.

Calorie posting is an important part of a broader effort to reduce overweight and obesity

70. Many social, behavioral, environmental, economic and biologic factors affect obesity and chronic disease, and the Department does not propose that calorie labeling

46

The Keystone Center. The Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity. Final Report. May 2006. Washington, D.C. [Report commissioned by the U.S. Food and Drug Administration.] URL: http://www.keystone.org/spp/documents/Forum_Report_FINAL_5-30-06.pdf.

Seymour JD, Yaroch AL, Serdula M, Blanck HM, Khan LK. Impact of nutrition environmental interventions on point-of-purchase behavior in public: a review. Prev Med 2004; 39: S108-S136

Case 1:08-cv-01000-RJH Document 33

alone can reverse this epidemic. It is one of a series of policy efforts being pursued to improve education and empower consumers by providing tools to support healthier choices. A recent edition of the Department's Health Bulletin series, "How to Lose Weight And Keep It Off' is just one publication that exemplifies the Department's educational approach for consumers. 103 Another is a recent issue of the Department's City Health Information series that assists health care providers in "Preventing and Managing Overweight and Obesity in Adults." 104 Attached hereto as Exhibit 12 are copies of these and another publication, "How Many Calories Do People Need Each Day?"

71. The Department and the City are undertaking a broad range of measures to help New Yorkers prevent or reverse weight gain, including new Health Code regulations for day care services that mandate minimum daily requirements of physical activities for very young children and improved nutritional standards; training and equipping more than 9,000 staff of children's institutions to lead physical activity sessions; promoting programs for physical activity in schools and offering free aerobics programs for adults; creating bicycle paths; outreach to medical providers on obesity management; and improvements in public food procurement and in food offerings in day cares, schools and other institutions. The need for additional actions to halt the obesity epidemic is no reason to refrain from taking the beneficial action of posting calorie information.

¹⁰³ NYC DOHMH. How to lose weight and keep it off. Health Bulletin (#51) 2007; 6(5).

¹⁰⁴ Berger DK, Lee KK, Silver LD. Preventing and Managing Overweight and Obesity in Adults. City Health Information. April/May 2007:26(4):23-30.

Summary

72. In summary, Health Code §81.50 is an important part of an integrated public response to the rapidly increasing epidemic of obesity and diabetes. The chain restaurants covered by the regulation have standardized food procurement and preparation, provide a large and apparently increasing proportion of food consumed by New Yorkers, and serve food higher in calories than food consumed at home, increasing the risk of obesity and with it, diabetes and other health problems. Calories are by far the single most important piece of nutritional information. Consumers are unaware of and generally underestimate caloric content. The manner in which chains currently make this information available, if they do so at all, is ineffective, with serious health consequences. There are consensus recommendations, broad evidence, and widespread scientific and social support for the rationale and soundness of this narrowly tailored measure and for the likelihood of it being effective in promoting more informed choices and healthier outcomes.

I declare under penalty of perjury pursuant to 28 U.S.C. §1746 that the foregoing is true and correct.

THOMAS R. FRIEDEN, M.D., M.P.H.

Executed on February 8, 2007

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Professional Experience:

Commissioner of Health and Mental Hygiene, New York City. 2002 -

Medical Officer, Tuberculosis Control, Southeast Asia Regional Office, World Health Organization (seconded from the Centers for Disease Control and Prevention). 1996 – 2002.

Technical Advisor, World Bank, Health and Population Offices, 1995 – 2001 (missions to India, Russia).

Assistant Commissioner of Health and Director, Bureau of Tuberculosis Control, New York City Department of Health. 1992 – 1996.

Supervisory Medical Officer, Centers for Disease Control and Prevention. 1995 - 2002

Medical Officer, Centers for Disease Control and Prevention. 1992 - 1995

Assistant Clinical Professor of Public Health (Epidemiology) Columbia University School of Public Health. 1993 – 2002.

Epidemic Intelligence Service Officer. Centers for Disease Control and Prevention. 1990 - 1992.

Fellow, Infectious Diseases. Yale University. 1989 - 1990.

Medical Resident. Columbia Presbyterian Medical Center (CPMC). 1986 - 1989.

Medical Supervisor. Psychiatry Shelter Program. CPMC. 1988 - 1989.

Mission leader to Nicaraguan Ministry of Health. 1983 – 1990 (various).

Founder and Editor, Links: Health and Development Report. 1983 –1991.

Summer Intern, New York Psychiatric Hospital, 1978.

Education:

Fellowship, Infectious Disease. Yale University. 1989 - 1990.

College of Physicians and Surgeons, Columbia University. 1982 - 1986. MD.

School of Public Health, Columbia University. 1985 - 1986. MPH.

Oberlin College, Ohio. 1978 - 1982. BA. *Summa cum laude*. Paul Robert Carey Foundation's Shining Spirit Award, 2007

Citizens' Committee for Children's Annual Founders' Award, 2007

Dean's Distinguished Service Award of the Mailman School of Public Health, Columbia University, 2007

Alexander D. Langmuir Memorial Lecture, 56th Annual Epidemic Intelligence Service Conference, 2007

Wheeling-Ohio County Health Department recognition for assistance in helping Ohio County (WV) pass its Clean Indoor Air Act

New York 1's New Yorker of the Year 2006

Princess Chichibu Memorial TB Global Award, 2006

Addiction Research & Treatment Corp.'s 2006 Humanitarian Service Award

Health Centers of New York City Leadership Award, 2006

Honorary Member, New York County Medical Society, June 2006

New York State Association of County Health Officials Public Health Professional of the Year 2006 Award

Governing Magazine's Public Official of the Year 2005 Award

Emily Dunning Barringer Award for Medical Achievement and Outstanding Public Service, 2005

Special Recognition Award, Community Health Care Association of New York State, 2004

Tobacco Control Leadership Award, National Council on Women's Health, 2003

William G. Cahan Memorial Education Award, American Cancer Society, 2003

Honor Award in International Health, Centers for Disease Control and Prevention, 2001

Award for Excellence, New York City Department of Health, 2001

Secretary's Award for Distinguished Service, Department of Health and Human Services, 1996

Excellence Award, National Center for HIV, STD, and TB
Prevention, Centers for Disease Control and Prevention, 1996

Special Recognition Award, Public Health Service, 1993

Excellence Award, Public Health Service, 1992

Achievement Medal, Public Health Service, 1992

Unit Commendation, Public Health Service, 1991

Distinguished Service Award. Douglas Community Health Council, 1982

Phi Beta Kappa. Oberlin College, 1982

Distinguished Service Award. New York Psychiatric Hospital, 1978

Certification:

Board Certified, Infectious Diseases. 1992 - 2002

Board Certified, Internal Medicine. 1989 - present

Diplomate, National Board of Medical Examiners. 1987

New York State Medical License. 1986.

Languages:

Spanish (fluent)

French (some speaking, reading)

Hindi (some understanding)

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(Revised 2/5/08 aic)

DEPARTMENT OF HEALTH AND MENTAL HYGIENE BOARD OF HEALTH

NOTICE OF ADOPTION OF AN AMENDMENT (§81.50) TO ARTICLE 81 OF THE NEW YORK CITY HEALTH CODE

In compliance with §1043(b) of the New York City Charter (the "Charter"), and pursuant to the authority granted to the Board of Health by §558 of said Charter, a Notice of Intention to amend Article 81 of the New York City Health Code, adding a new §81.50, was published in the City Record on September 29, 2006, and a public hearing was held on October 30, 2006. More than 2,200 written and oral comments were received, including testimony from 45 persons who testified at the public hearing. At its meeting on December 5, 2006, the Board of Health adopted the following resolution.

STATUTORY AUTHORITY

This amendment to the Health Code is promulgated pursuant to §§558 and 1043 of the Charter. Section 558(b) and (c) of the Charter empowers the Board of Health to amend the Health Code and to include in the Health Code all matters to which the Department's authority extends. Section 1043 grants the Department rule-making authority.

STATEMENT OF BASIS AND PURPOSE

The Department of Health and Mental Hygiene (the "Department") enforces provisions of the New York City Health Code ("Health Code") and other applicable law relating to food served directly to the consumer throughout the City, including food that is commercially prepared, and sold or distributed for free, by food service establishments, a broad category which includes restaurants, caterers and mobile food vending units. The Department also regulates non-retail food processing establishments, such as mobile food vending commissaries, as defined in Health Code §89.01, which supply food for mobile vending units.

Background

Restaurants (the term is being used interchangeably with "food service establishments" or "FSEs") are an important source of daily food intake for New York City residents: an estimated one third of daily caloric intake comes from foods purchased outside of the home. Assuring safe and healthy dining options is a public health priority. The Department issues permits and inspects all New York City FSEs and non-retail food processing establishments, as defined in \$81.03(j) and (p) of the Health Code. Although federally mandated nutrition labeling on food products for sale in supermarkets facilitates informed choice, consumers lack such essential information to make healthy choices when eating in restaurants. Calorie information, if provided at the time of food selection, would allow New Yorkers to make more informed choices. Accordingly, Article 81 of the New York City Health Code is being amended to require that information on calorie content values of menu items be available to patrons of FSEs at the time of ordering when such information is otherwise made publicly available by or on behalf of the FSEs.

The Department is charged with preventing and controlling diseases, including chronic disease, through approaches that may address individual behavior or the community environment. By requiring posting of available information concerning restaurant menu item calorie content, so that such information is accessible at the time of ordering, this Health Code amendment will allow individuals to make more informed choices that can decrease their risk for the negative health effects of overweight and obesity associated with excessive calorie intake.

Obesity is epidemic

According to measured height and weight data from the National Health and Nutrition Examination Survey (NHANES), the obesity rate among U.S. adults more than doubled over the past three decades from 14.5% in 1971-1974 to 32.2% in 2003-2004.^{2,3} In New York City, more than half of adults are overweight and one in six is obese. 4 Obesity begins early - 21% of New York City kindergarten children are obese.⁵ People who are overweight are at increased risk for diabetes, heart disease, stroke, high blood pressure, arthritis, and cancer. Diagnosed diabetes more than doubled over the past decade and now affects three quarters of a million New Yorkers.⁶

If rates of obesity continue to rise unabated, it has been estimated that one in three children (and half of Hispanic children) born in 2000 will develop diabetes in his or her lifetime.

'Away from Home' food consumption increasingly fuels obesity and chronic illness

Americans are increasingly eating meals away from home. In 1970, Americans spent 26% of their food dollars on foods prepared outside their homes while by 2006 they spent almost half (48%) of their food dollars eating out.⁸ As previously noted, the average American consumes about one third of calories from foods from restaurants. Children eat almost twice as many calories when they eat out than when they eat at home.¹⁰

Nutrition labeling works and is supported by consumers and leading experts

Since 1994, the federal Nutrition Labeling and Education Act (NLEA) has made nutrition information available to consumers on packaged foods purchased in retail stores. This information is widely used. Three-quarters of American adults report using food labels, 11 and about half (48%) report that nutrition information on food labels has caused them to change their food purchasing habits.¹² However, NLEA explicitly exempts restaurants from nutrition labeling requirements, and at most restaurants, people can only guess the nutrient content of foods at the point of purchase. Current voluntary attempts by some food service establishments to make available nutrition information are inadequate particularly because the information is usually not displayed where consumers are making their choices and purchases. When FSEs' nutrition information is available on the internet, patrons need to have access to off-site websites. Such information may also be available in brochures, on placemats covered with food items, or on food wrappers, where the information is hard to find or difficult to read and only accessible after the purchase is made. Thus the information provided has little impact on choice. 13

Without calorie information, it is difficult for consumers to compare options and make informed decisions. People do not accurately guess the calorie content of foods and beverages, and calorie information will help guide food choices. Recent studies found that 9 out of 10 people underestimated the calorie content of less-healthy items by an average of more than 600 calories (almost 50% less than the actual calorie content). 14 When calorie information was provided on food items, consumers chose highcalorie items 24% to 37% less often.

Additional marketing research has shown that providing nutrition information affects consumer attitudes and purchasing intentions. Consumers consistently underestimate the nutrient levels in food items and overestimate the healthfulness of restaurant items. 15 When consumers are made aware of nutrition information at the point of purchase, disease risk perceptions increase, attitudes toward the product change, and purchasing intentions for unhealthy products decrease. 16,17 Presenting nutrition information on restaurant menus empowers consumers and influences food choices. 18

Studies consistently show that consumers would like to have this information. Six nationally representative polls have found that between 62% to 87% of Americans support requiring restaurants to list nutrition information. 19,20

A key recommendation of a recent Food and Drug Administration-sponsored expert group report on obesity and eating away from the home was that, "Away-from-home food establishments should provide consumers with calorie information in a standard format that is easily accessible and easy to use. Participants believe that information should be provided in a manner that is easy for consumers to see and use as part of their purchasing and eating decisions. Information should be provided for any standard menu item offered on a regular and ongoing basis that is prepared from a standardized recipe, whether the item is an entire meal or a meal component. Non-standard items, including daily specials and experimental items, may be exempted. Information should be provided for the standard menu item as usually offered for sale (i.e., the base product, in the portion size as offered for sale), since most means of providing information cannot easily account for changes due to customization and special orders."²¹

Changes to Health Code to require calorie labeling

New York City needs to address the rapidly growing twin epidemics of obesity and diabetes. Calorie labeling is a public heath intervention to help address these problems. Providing simple, point-ofpurchase calorie information would allow consumers to make more informed food choices in restaurants just as they currently can in supermarkets.

As amended, Health Code §81.50 requires FSEs that make calorie information for standardized menu items publicly available (published by or on behalf of the FSE) on or after March 1, 2007, to post such calorie (kcal) information on menu boards and menus, next to each menu item (Figure 1). Of course, in order for the calorie information to be accurate, such a requirement can only be implemented for food items that are standardized with regard to portion size, formulation, and ingredients. Therefore, it is expected that the proposal would apply only to the approximately 10% of New York City food service establishments that serve food menu items in portions that are standardized for size and content and currently post calorie information on these items. Posting of calorie content information will be required for any menu items for which calorie content has been made publicly available. Calorie amounts shall be posted in a size and typeface at least as large as the price or name of the menu item. This provision does not require any FSE to engage in analysis of the nutrition content of its menu items, but does require restaurants that make such information publicly available to their customers to post it in plain sight, so it is available at the time of ordering. By doing so, these FSEs will enable New Yorkers to have the information they need to make more informed choices.

MENU	Calories	Price
HAMBURGER	280	.89
CHEESEBURGER	330	.99
FISH FILET	470	1.99
CRUNCHY CHICKEN	550	2.79
4 OZ HAMBURGER	430	2.29
EXTRA BIG HAMBURGER	540	2.29
BIG BIG BURGER	590	2.39
GRILLED CHICKEN	450	2.89
8 OZ BURGER	760	2.99

FIGURE 1: Example of Menu Board with Calorie Labeling²²

Only FSEs that make nutritional information publicly available on or after March 1, 2007, such as in brochures, signage, websites, or other means, will be required to post calorie information. Posted calorie content information will be calculated in accordance with 21 CFR §101.9(c)(1)(i) or its successor regulation. FSEs would not be precluded from providing additional nutrition information voluntarily.

The Department's restaurant inspectors would be responsible for enforcing the requirement that nutrition information is provided on menu boards and menus.

Changes made in response to public comments

Substantial support was received for the proposal in written comments and oral testimony. Of the approximately 2,200 written and oral comments received, all but 22 supported the amendment. The proposal has been further amended in response to the comments and for clarity. To clearly identify the number of calories displayed, as in Figure 1, above, FSEs will be required to place the word "calories" or "cal" as a heading above the column listing the number of calories, or adjacent to the calorie content value for each menu item. In response to comments that requiring display of the median calorie content value for menu items offered in a range of flavors or varieties could be confusing, the proposal has been amended so that FSEs will now be required to display the range (minimum to maximum) of calories applicable to all flavors or varieties rather than calculating the median number of calories for the menu item. Finally, FSEs will also be allowed to exercise flexibility in how they display calorie information at the point of purchase, subject to the Department's prior approval.

STATEMENT PURSUANT TO SECTION 1042 – REGULATORY AGENDA

The proposed amendment was not included in the Department's Regulatory Agenda because it resulted from a recent analysis by the Department.

The proposal is as follows:

Note-matter in brackets [] to be deleted Matter <u>underlined</u> is new

RESOLVED, that Article 81 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, as last amended by resolution adopted on the seventh of June, two thousand five, be, and the same hereby is further amended, to add a new section 81.50, to be printed with explanatory notes, as follows:

§81.50 Calorie labeling.

- (a) Scope and applicability. This section shall apply to menu items that are served in portions the size and content of which are standardized and for which calorie content information is made publicly available on or after March 1, 2007, by or on behalf of the food service establishment serving the items.
- (b) Calorie information for menu items. Food service establishments shall post on menu boards and menus the calorie content values (in kcal) that have been made publicly available as specified in subdivision (a) for each menu item next to the listing of each menu item. Posted calorie content shall be calculated in accordance with 21 CFR §101.9(c)(1)(i) or its successor regulation. Subject to prior approval by the Department, food service establishments may use alternative means for making calorie

information available to patrons, provided such information is made available at the point of purchase and is at least as prominent as required in paragraph (1) below.

- (1) Menu boards and menus. The term "calories" or "cal" shall appear as a heading above a column listing the calorie content value of each menu item, or adjacent to the calorie content value for each menu item, in the same or larger typeface as the calorie content values for individual menu items.
- (A) Menu boards. On menu boards, calorie content values shall be posted in a size and typeface at least as large as the name of the menu item or price, whichever is larger.
- (B) Menus. On printed menus, calorie content values shall be legible and shall be printed in a size and typeface at least as large as the name or price of the menu item.
- (2) Range of calorie content values for different flavors and varieties. For menu items that come in different flavors and varieties but that are listed as a single menu item, including, but not limited to, beverages, ice cream, pizza or doughnuts, the range of calorie content values showing the minimum to maximum numbers of calories for all flavors or varieties of that item shall be listed on menu boards and menus for each size offered for sale.
- (c) Effective date. This section shall take effect on July 1, 2007.

Notes: Section 81.50 was added by resolution adopted on December 5, 2006 to require that food service establishments in New York City that sell food items whose portion size and content are standardized prominently display publicly available information about the calorie content of such items on menu boards and menus in an effort to facilitate patrons' nutritional choices at time of purchase.

RESOLVED, that the list of Section Headings in Article 81 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, as amended by resolution adopted on the seventh of June, two thousand five, be, and the same hereby is, further amended, to be printed together with explanatory notes, as follows:

ARTICLE 81

FOOD PREPARATION AND FOOD ESTABLISHMENTS

*

§81.49 Modification by Commissioner.

§81.50 Calorie labeling.

§81.51 Examination of most recent inspection report by patron or customer; posting sign.

Notes: The Table of Section Headings was further amended when a new §81.50 was added by resolution adopted on December 5, 2006 to require that food service establishments in New York City that sell food items whose portion size and content are standardized prominently display publicly available information about the calorie content of such items on menu boards and menus in an effort to facilitate patrons' nutritional choices at time of purchase.

S: HC 81.50 adopt

Guthrie JF. et al. Role of Food Prepared Away from Home in the American Diet, 1977-78 Versus 1994-96: Changes and Consequences. Society for Nutrition Education 2002; 34:140-150.

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Statements. November 9, 2004. P. 28-29. URL: http://www.apha.org/legislative/policy/2004/2004-14.pdf

¹⁴ Burton S. Creyer EH. et al. Attacking the obesity epidemic: the potential health benefits of providing nutrition information in restaurants. *Am J Public Health*. 2006; 96(9):1669-1675.

15 Burton S. Creyer EH. What consumers don't know *can* hurt them: Consumer evaluations and disease risk perceptions of

restaurant menu items. The Journal of Consumer Affairs. 2004; 38(1):121-145.

¹⁶ Burton S. Creyer EH. What consumers don't know can hurt them: Consumer evaluations and disease risk perceptions of restaurant menu items. The Journal of Consumer Affairs. 2004; 38(1):121-145.

¹⁷ Kozup JC. Creyer EH. Burton S. Making Healthful Food Choices: The Influence of Health Claims and Nutrition Information on Consumers' Evaluations of Packaged Food Products and Restaurant Menu Items. Journal of Marketing. 2003; 67:19-34.

¹⁸ Burton S. Creyer EH. What consumers don't know can hurt them: Consumer evaluations and disease risk perceptions of restaurant menu items. The Journal of Consumer Affairs. 2004; 38(1):121-145.

¹⁹ Center for Science in the Public Interest. Anyone's Guess: The need for nutrition labeling at fast-food and other chain restaurants. Washington, DC: Center for Science in the Public Interest, 2003.

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The Surgeon General's
Call To Action
To Prevent and Decrease
Overweight and Obesity
2001



U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service
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Filed 02/15/2008 Page 2 of 39

In Memory of PAUL AMBROSE, M.D., M.P.H.

(December 26, 1968–September 11, 2001)

Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services

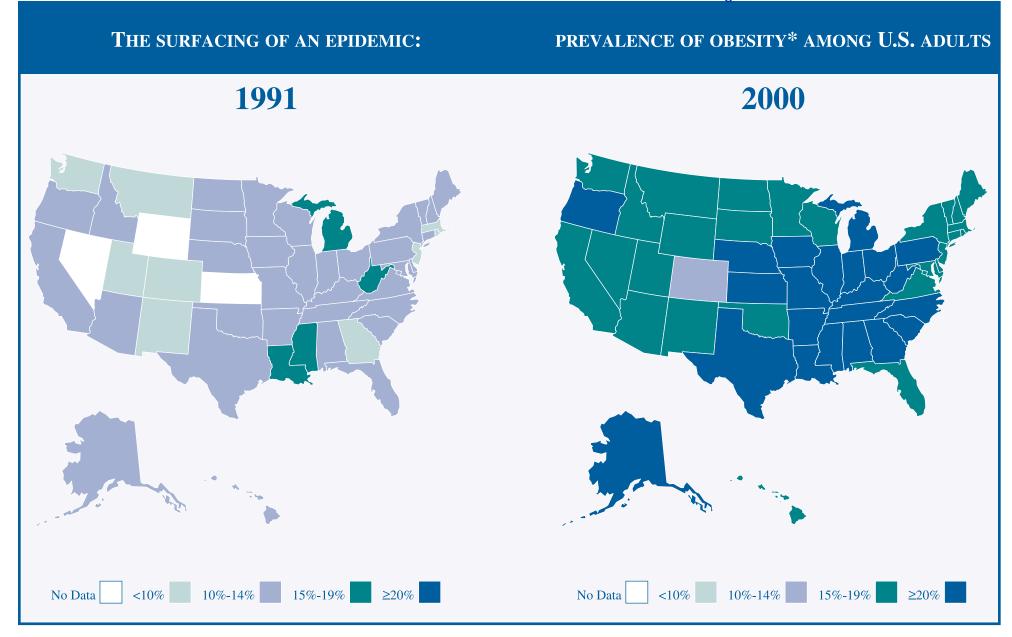
As senior editor of this *Call To Action*, Dr. Ambrose's commitment to promoting public health and preventing disease was a critical force in the development of this document.

A Call To Action To Prevent and Decrease Overweight and Obesity

PRINCIPLES:

Overweight and obesity have reached nationwide epidemic proportions. Both the prevention and treatment of overweight and obesity and their associated health problems are important public health goals. To achieve these goals, *The Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity* is committed to five overarching principles:

- Promote the recognition of overweight and obesity as major public health problems.
- Assist Americans in balancing healthful eating with regular physical activity to achieve and maintain a healthy or healthier body weight.
- Identify effective and culturally appropriate interventions to prevent and treat overweight and obesity.
- Encourage environmental changes that help prevent overweight and obesity.
- Develop and enhance public-private partnerships to help implement this vision.



These two figures demonstrate the increasing prevalence of obesity* among U.S. adults

*Approximately 30 pounds overweight

Source: Behavioral Risk Factor Surveillance System (BRFSS)

Note: BFRSS uses self-reported height and weight to calculate obesity; self-reported data may underestimate obesity prevalence.

The Surgeon General's Call To Action To Action

and Human Services	X
Foreword From the Surgeon General, U.S. Department of Health and Human Services	
Section 1: Overweight and Obesity as Public Health Problems in America	1
Measuring Overweight and Obesity	
Health Risks	8
Economic Consequences	9
Epidemiology	10
Disparities in Prevalence	13
Health Benefits of Weight Loss	14
Section 2: Posing Questions and Developing Strategies	14
Developing a Public Health Response	
CARE to Address Overweight and Obesity	
Setting 1: Families and Communities	
Setting 2: Schools	
Setting 3: Health Care	
Setting 4: Media and Communications	
Setting 5: Worksites	
Section 3: The Power of People and Ideas	
Creating National Action	
Sustaining National Action	30
Section 4: Vision for the Future	33
Surgeon General's Priorities for Action	
Conclusion	
	25
References	3
Acknowledgments	41
Steering Committee Roster	43
Steering Committee Roster	4.
Appendix A: Examples of Federal Programs and Initiatives	45
Appendix B: Federal Program Resource List	53

Message From the Secretary U.S. Department of Health and

The 20th century saw remarkable and unprecedented improvements in the lives of the people of our country. We saw the infant mortality rate plummet and life expectancy increase by 30 years. Deaths from infectious diseases dropped tremendously, and improvements in medical care allowed many individuals with chronic disease to lead longer, fuller lives. Yet despite these and other successes, complex new health challenges continue to confront us.

Human Services

Overweight and obesity are among the most important of these new health challenges. Our modern environment has allowed these conditions to increase at alarming rates and become highly pressing health problems for our Nation. At the same time, by confronting these conditions, we have tremendous opportunities to prevent the unnecessary disease and disability that they portend for our future.

As we move to acknowledge and understand these conditions, it is important to remember that they are as sensitive for each of us as they are challenging and important for our country's health. This is truly the time for a *Call To Action*, because each one of us as an individual must understand that we are called upon to act, just as our institutions are called upon to consider how they can help confront this new epidemic.

This Surgeon General's *Call To Action* represents an opportunity for individuals to make healthy lifestyle choices for themselves and their families. It encourages health care providers to help individuals prevent and treat these conditions. At a broader level, it prompts all communities to make changes that promote healthful eating and adequate physical activity. It calls for scientists to pursue new research. Above all, it calls upon individuals, families, communities, schools, worksites, organizations, and the media to work together to build solutions that will bring better health to everyone in this country.

I wholeheartedly support *The Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity*, and I urge all of us to work together to achieve its ambitious and essential vision.

Like many across the Nation, the Department of Health and Human Services was reminded how small the world is when, on September 11, we lost one of our own, Paul Ambrose, M.D., M.P.H. He had just finished the final edits on the *Call To Action* and was on his way to a conference in California on childhood obesity when tragedy struck. Paul was a man of great compassion and heart, committed to helping people in rural America obtain better health care and improving prevention measures for all Americans. He cared deeply for the issues he worked on but even more for the people affected. While we will miss Paul's energy and dedication, we will miss his humanity even more.

Tommy G. Thompson

Filed 02/15/2008 Page 7 of 39

Foreword From the Surgeon General

U.S. Department of Health and Human Services

Overweight and obesity may not be infectious diseases, but they have reached epidemic proportions in the United States. Overweight and obesity are increasing in both genders and among all population groups. In 1999, an estimated 61 percent of U.S. adults were overweight or obese, and 13 percent of children and adolescents were overweight. Today there are nearly twice as many overweight children and almost three times as many overweight adolescents as there were in 1980. We already are seeing tragic results from these trends. Approximately 300,000 deaths a year in this country are currently associated with overweight and obesity. Left unabated, overweight and obesity may soon cause as much preventable disease and death as cigarette smoking.

Overweight and obesity have been grouped as one of the Leading Health Indicators in *Healthy People 2010*, the Nation's health objectives for the first decade of the 21st century. The Leading Health Indicators reflect the major public health concerns and opportunities in the United States. While we have made dramatic progress over the last few decades in achieving so many of our health goals, the statistics on overweight and obesity have steadily headed in the wrong direction. If this situation is not reversed, it could wipe out the gains we have made in areas such as heart disease, diabetes, several forms of cancer, and other chronic health problems. Unfortunately, excessive weight for height is a risk factor for all of these conditions.

Many people believe that dealing with overweight and obesity is a personal responsibility. To some degree they are right, but it is also a community responsibility. When there are no safe, accessible places for children to play or adults to walk, jog, or ride a bike, that is a community responsibility. When school lunchrooms or office cafeterias do not provide healthy and appealing food choices, that is a community responsibility. When new or expectant mothers are not educated

about the benefits of breastfeeding, that is a community responsibility. When we do not require daily physical education in our schools, that is also a community responsibility. There is much that we can and should do together.

Taking action to address overweight and obesity will have profound effects on increasing the quality and years of healthy life and on eliminating health disparities in the United States. With this outcome in mind, I asked the Office of Disease Prevention and Health Promotion, along with other agencies in the Department of Health and Human Services, to assist me in developing this Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity. Our ultimate goal is to set priorities and establish strategies and actions to reduce overweight and obesity. This process begins with our attitudes about overweight and obesity. Recognition of the epidemic of overweight and obesity is relatively recent, and there remain enormous challenges and opportunities in finding solutions to this public health crisis. Overweight and obesity must be approached as preventable and treatable problems with realistic and exciting opportunities to improve health and save lives. The challenge is to create a multifaceted public health approach capable of delivering long-term reductions in the prevalence of overweight and obesity. This approach should focus on health rather than appearance and empower both individuals and communities to address barriers, reduce stigmatization, and move forward in addressing overweight and obesity in a positive and proactive fashion.

Several events have drawn attention to overweight and obesity as public health problems. In 1998, the National Heart, Lung, and Blood Institute in cooperation with the National Institute of Diabetes and Digestive and Kidney Diseases of the National Institutes of Health released the Clinical Guidelines on the Identification, Evaluation, and Treatment of Obesity in Adults: Evidence Report. This report was the result of a thorough scientific review of the evidence related to the risks and treatment of overweight and obesity, and it provided evidence-based treatment guidelines for health care providers. In early 2000, the release of Healthy People 2010 identified overweight and obesity as major public health problems and set national objectives for reduction in their prevalence. The National Nutrition Summit in May 2000 illuminated the impact of dietary and physical activity habits on achieving a healthy body weight and began a national dialogue on strategies for the prevention of overweight and obesity. Finally, a Surgeon General's Listening Session, held in late 2000, and a related public comment period, generated many useful ideas for prevention and treatment strategies and helped forge and reinforce an important coalition of stakeholders. Participants in these events considered many prevention and treatment strategies, including such national priorities as ensuring daily physical education in schools, increasing research on the behavioral and environmental causes of obesity, and promoting breastfeeding.

These activities are just a beginning, however. Effective action requires the close cooperation and collaboration of a variety of organizations and individuals. This Call To Action serves to recruit your talent and inspiration in developing national actions to promote healthy eating habits and adequate physical activity, beginning in childhood and continuing across the lifespan. I applaud your interest in this important public health challenge.

David Satcher, M.D., Ph.D.

Dun Tortcher

XIV

Filed 02/15/2008 Page 9 of 39

Section 1:

Overweight and Obesity as Public Health Problems in America

This Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity seeks to engage leaders from diverse groups in addressing a public health issue that is among the most burdensome faced by the Nation: the health consequences of overweight and obesity. This burden manifests itself in premature death and disability, in health care costs, in lost productivity, and in social stigmatization. The burden is not trivial. Studies show that the risk of death rises with increasing weight. Even moderate weight excess (10 to 20 pounds for a person of average height) increases the risk of death, particularly among adults aged 30 to 64 years.¹

Overweight and obesity are caused by many factors. For each individual, body weight is determined by a combination of genetic, metabolic, behavioral, environmental, cultural, and socioeconomic influences. Behavioral and environmental factors are large contributors to overweight and obesity and provide the greatest opportunity for actions and interventions designed for prevention and treatment.

For the vast majority of individuals, overweight and obesity result from excess calorie consumption and/or inadequate physical activity. Unhealthy dietary habits and sedentary behavior together account for approximately 300,000 deaths every year.^{2,3} Thus, a healthy diet and regular physical activity, consistent with the *Dietary Guidelines for Americans*, should be promoted as the cornerstone of any prevention or treatment effort.^{4,5} According to the U.S. Department of Agriculture's 1994–1996 Continuing Survey of Food Intakes by Individuals, very few Americans meet the majority of the Food Guide Pyramid recommendations. Only 3 percent of all individuals meet four of the five recommendations for the intake of grains, fruits, vegetables, dairy products, and meats.⁶ Much work needs to be done to ensure the nutrient adequacy of our diets while at the same time avoiding excess calories. Dietary adequacy and moderation in energy consumption are both important for maintaining or achieving a healthy weight and for overall health.

Many adult Americans have not been meeting Federal physical activity recommendations to accumulate at least 30 minutes of moderate physical activity most days of the week.^{4,7} In 1997, less than one-third of adults engaged in the recommended amount of physical activity, and 40 percent of adults engaged in no leisure-time physical activity.⁷ Although nearly 65 percent of adolescents reported participating in vigorous activity for 20 minutes or more on 3 or more out of 7 days, national data are not available to assess whether children and adolescents meet the Federal recommendations to accumulate at least 60 minutes of moderate physical activity most days of the week.^{4,8} Many experts also believe that physical *inactivity* is an important part of the energy imbalance responsible for the increasing prevalence of overweight and obesity. Our society has become very sedentary; for example, in 1999, 43 percent of students in grades 9 through 12 viewed television more than 2 hours per day.⁸

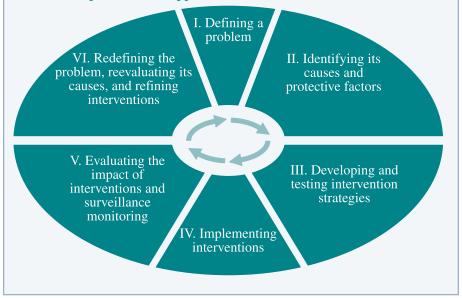
Both dietary intake and physical activity are difficult to measure on either an individual or a population level. More research is clearly necessary to fully understand the specific etiology of this crisis. However, these statistics and the increasing prevalence of overweight and obesity highlight the need to engage all Americans as we move forward to ensure the quality and accessibility of prevention and treatment programs.

PUBLIC HEALTH AND THE SURGEON GENERAL

Through cooperative action, public health programs have successfully prevented the spread of infectious disease, protected against environmental hazards, reduced accidents and injuries, responded to disasters, worked toward ensuring the quality and accessibility of health services, and promoted healthy behaviors. Over the past 100 years, thanks largely to public health efforts, the life expectancy of Americans has increased by approximately 50 percent.

Public health success has traditionally come from the reduction in the incidence of infectious diseases through improved sanitation and nutrition, cleaner air and water, and national vaccination programs. As the threats to America's health have shifted, so too have public health efforts. In recent years, public health efforts have successfully navigated new frontiers such as violence prevention, tobacco cessation, and mental health. Public health officials remain poised to address new health challenges through the collaborative processes of scientific research, policy development, and community mobilization.

The public health approach involves a circle of activities:



MEASURING OVERWEIGHT AND OBESITY

The first challenge in addressing overweight and obesity lies in adopting a common public health measure of these conditions. An expert panel, convened by the National Institutes of Health (NIH) in 1998, has utilized Body Mass Index (BMI) for defining overweight and obesity. BMI is a practical measure that requires only two things: accurate measures of an individual's weight and height (figure 1). BMI is a measure of weight in relation to height. BMI is calculated as weight in pounds divided by the square of the height in inches, multiplied by 703. Alternatively, BMI can be calculated as weight in kilograms divided by the square of the height in meters.

Studies have shown that BMI is significantly correlated with total body fat content for the majority of individuals. BMI has some limitations, in that it can overestimate body fat in persons who are very muscular, and it can underestimate body fat in persons who have lost muscle mass, such as many elderly. Many organizations, including over 50 scientific and medical organizations that have endorsed the NIH *Clinical Guidelines*, support the use of a BMI of 30 kg/m² or greater to identify obesity in adults and a BMI between 25 kg/m² and 29.9 kg/m² to identify overweight in adults. 12,13 These definitions are based on evidence that suggests health risks are greater at or above a BMI of 25 kg/m² compared to those at a BMI below that level. 12 The risk of death, although modest until a BMI of 30 kg/m² is reached, increases with an increasing Body Mass Index. 1

FIGURE 1: ADULT BODY MASS INDEX

BMI=
$$\left\{ \frac{\text{WEIGHT (pounds)}}{\text{HEIGHT (inches)}^2} \right\} \times 703$$

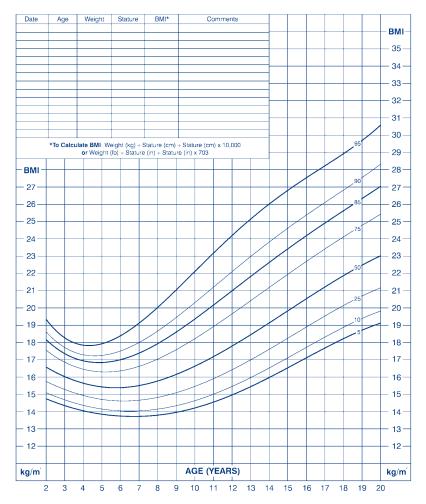
Weight in Pounds

	Troisit in a variab														
		120	130	140	150	160	170	180	190	200	210	220	230	240	250
Height in Feet and Inches	4'6	29	31	34	36	39	41	43	46	48	51	53	56	58	60
	4'8	27	29	31	34	36	38	40	43	45	47	49	52	54	56
	4'10	25	27	29	31	34	36	38	40	42	44	46	48	50	52
	5'0	23	25	27	29	31	33	35	37	39	41	43	45	47	49
	5'2	22	24	26	27	29	31	33	35	37	38	40	42	44	46
	5'4	21	22	24	26	28	29	31	33	34	36	38	40	41	43
	5'6	19	21	23	24	26	27	29	31	32	34	36	37	39	40
	5'8	18	20	21	23	24	26	27	29	30	32	34	35	37	38
	5'10	17	19	20	22	23	24	26	27	29	30	32	33	35	36
	6'0	16	18	19	20	22	23	24	26	27	28	30	31	33	34
	6'2	15	17	18	19	21	22	23	24	26	27	28	30	31	32
	6'4	15	16	17	18	20	21	22	23	24	26	27	28	29	30
	6'6	14	15	16	17	19	20	21	22	23	24	25	27	28	29
	6'8	13	14	15	17	18	19	20	21	22	23	24	25	26	28

Healthy Weight Overweight Obese

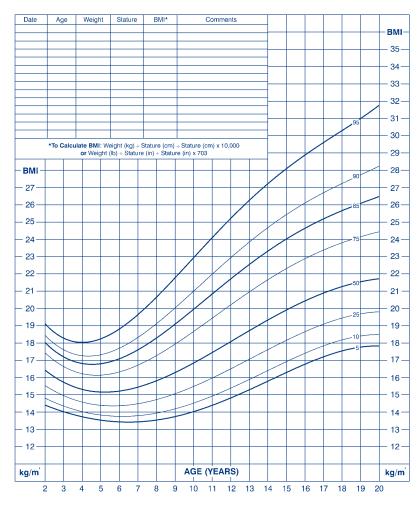
In children and adolescents, overweight has been defined as a sex- and agespecific BMI at or above the 95th percentile, based on revised Centers for Disease Control and Prevention (CDC) growth charts (figures 2 and 3).¹⁴ Neither a separate definition for obesity nor a definition for overweight based on health outcomes or risk factors is defined for children and adolescents.¹⁵

FIGURE 2: BODY MASS INDEX-FOR-AGE PERCENTILES: BOYS AGED 2 TO 20 YEARS



Source: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000)

FIGURE 3: BODY MASS INDEX-FOR-AGE PERCENTILES:
GIRLS AGED 2 TO 20 YEARS



Source: Developed by the National Center for Health Statistics in collaboration with the National Center for Chronic Disease Prevention and Health Promotion (2000)

HEALTH RISKS

Epidemiological studies show an increase in mortality associated with overweight and obesity. Individuals who are obese (BMI \geq 30) have a 50 to 100 percent increased risk of premature death from all causes compared to individuals with a BMI in the range of 20 to 25. An estimated 300,000 deaths a year may be attributable to obesity.

Morbidity from obesity may be as great as from poverty, smoking, or problem drinking.¹⁷ Overweight and obesity are associated with an increased risk for coronary heart disease; type 2 diabetes; endometrial, colon, postmenopausal breast, and other cancers; and certain musculoskeletal disorders, such as knee osteoarthritis (table 1).¹⁸ Both modest and large weight gains are associated with significantly increased risk of disease. For example, a weight gain of 11 to 18 pounds increases a person's risk of developing type 2 diabetes to twice that of individuals who have not gained weight, while those who gain 44 pounds or more have four times the risk of type 2 diabetes.¹⁹

A gain of approximately 10 to 20 pounds results in an increased risk of coronary heart disease (nonfatal myocardial infarction and death) of 1.25 times in women²⁰ and 1.6 times in men.²¹ Higher levels of body weight gain of 22 pounds in men and 44 pounds in women result in an increased coronary heart disease risk of 1.75 and 2.65, respectively.^{20,21} In women with a BMI of 34 or greater, the risk of developing endometrial cancer is increased by more than six times.²² Overweight and obesity are also known to exacerbate many chronic conditions such as hypertension and elevated cholesterol.²³ Overweight and obese individuals also may suffer from social stigmatization, discrimination, and poor body image.²⁴

Although obesity-associated morbidities occur most frequently in adults, important consequences of excess weight as well as antecedents of adult disease occur in overweight children and adolescents. Overweight children and adolescents are more likely to become overweight or obese adults; this concern is greatest among adolescents. Type 2 diabetes, high blood lipids, and hypertension as well as early maturation and orthopedic problems also occur with increased frequency in overweight youth. A common consequence of childhood overweight is psychosocial—specifically discrimination.²⁵

These data on the morbidity and mortality associated with overweight and obesity demonstrate the importance of the prevention of weight gain, as well as the role of obesity treatment, in maintaining and improving health and quality of life.

TABLE 1: HEALTH RISKS ASSOCIATED WITH OBESITY

Obesity is Associated with an Increased Risk of:

- premature death
- type 2 diabetes
- · heart disease
- stroke
- hypertension
- gallbladder disease
- osteoarthritis (degeneration of cartilage and bone in joints)
- · sleep apnea
- asthma
- breathing problems
- cancer (endometrial, colon, kidney, gallbladder, and postmenopausal breast cancer)

- high blood cholesterol
- complications of pregnancy
- menstrual irregularities
- hirsutism (presence of excess body and facial hair)
- stress incontinence (urine leakage caused by weak pelvic-floor muscles)
- increased surgical risk
- psychological disorders such as depression
- psychological difficulties due to social stigmatization

Adapted from www.niddk.nih.gov/health/nutrit/pubs/statobes.htm²⁶

ECONOMIC CONSEQUENCES

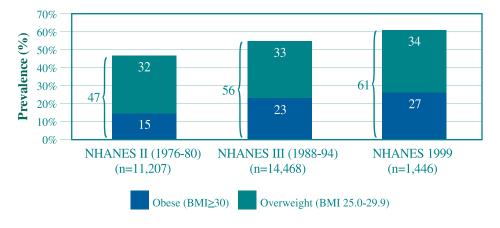
Overweight and obesity and their associated health problems have substantial economic consequences for the U.S. health care system. The increasing prevalence of overweight and obesity is associated with both direct and indirect costs. Direct health care costs refer to preventive, diagnostic, and treatment services related to overweight and obesity (for example, physician visits and hospital and nursing home care). Indirect costs refer to the value of wages lost by people unable to work because of illness or disability, as well as the value of future earnings lost by premature death.²⁷

In 1995, the total (direct and indirect) costs attributable to obesity amounted to an estimated \$99 billion.²⁷ In 2000, the total cost of obesity was estimated to be \$117 billion (\$61 billion direct and \$56 billion indirect).²⁸ Most of the cost associated with obesity is due to type 2 diabetes, coronary heart disease, and hypertension.²⁹

EPIDEMIOLOGY

The United States is experiencing substantial increases in overweight and obesity (as defined by a BMI \geq 25 for adults) that cut across all ages, racial and ethnic groups, and both genders. According to self-reported measures of height and weight, obesity (BMI \geq 30) has been increasing in every State in the Nation. Based on clinical height and weight measurements in the 1999 National Health and Nutrition Examination Survey (NHANES), 34 percent of U.S. adults aged 20 to 74 years are overweight (BMI 25 to 29.9), and an additional 27 percent are obese (BMI \geq 30). This contrasts with the late 1970s, when an estimated 32 percent of adults aged 20 to 74 years were overweight, and 15 percent were obese (figure 4).

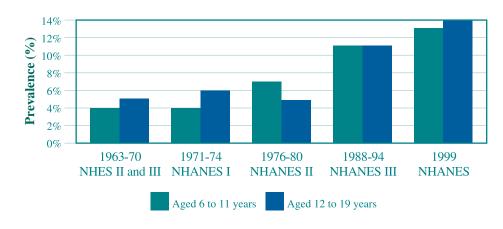
Figure 4: Age-adjusted prevalence of overweight and obesity among U.S. adults aged 20 to 74 years



Source: Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS), National Health and Nutrition Examination Survey (NHANES)

The most recent data (1999) estimate that 13 percent of children aged 6 to 11 years and 14 percent of adolescents aged 12 to 19 years are overweight.³³ During the past two decades, the percentage of children who are overweight has nearly doubled (from 7 to 13 percent), and the percentage of adolescents who are overweight has almost tripled (from 5 to 14 percent) (figure 5).³³

FIGURE 5: PREVALENCE OF OVERWEIGHT* AMONG U.S. CHILDREN AND ADOLESCENTS



*Gender- and age-specific BMI ≥ the 95th percentile Source: Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS) National Health Examination Survey (NHES), National Health and Nutrition Examination Survey (NHANES)

DISPARITIES IN PREVALENCE

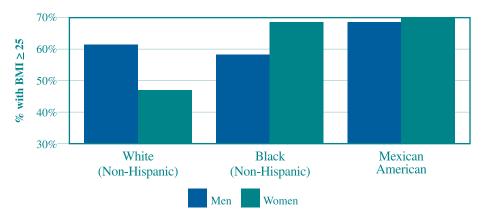
Between the second and third National Health and Nutrition Examination Surveys (NHANES II and III), the prevalence of overweight and obesity (BMI \geq 25 for adults and \geq 95th percentile for age and gender in children) increased in both genders, across all races and ethnicities, and across all age groups. ^{15,30} Disparities in overweight and obesity prevalence exist in many segments of the population based on race and ethnicity, gender, age, and socioeconomic status. For example, overweight and obesity are particularly common among minority groups and those with a lower family income.

RACE AND ETHNICITY, GENDER, AND AGE

In general, the prevalence of overweight and obesity is higher in women who are members of racial and ethnic minority populations than in non-Hispanic white women. Among men, Mexican Americans have a higher prevalence of overweight and obesity than non-Hispanic whites or non-Hispanic blacks. For non-Hispanic men, the prevalence of overweight and obesity among whites is slightly greater than among blacks.³⁰

Within racial groups, gender disparities exist, although not always in the same direction. Based on NHANES III (1988–1994),³⁰ the proportion of non-Hispanic black women who were overweight or obese (BMI \geq 25; 69 percent) was higher than the proportion of non-Hispanic black men (58 percent) (figure 6). For non-Hispanic whites, on the other hand, the proportion of men who were overweight or obese (BMI \geq 25; 62 percent) exceeded the proportion of women (47 percent). However, when looking at obesity alone (BMI \geq 30), the prevalence was slightly higher in non-Hispanic white women compared to non-Hispanic white men (23 percent and 21 percent, respectively).³⁰ The prevalence of overweight or obesity (BMI \geq 25) was about the same in Mexican American men and women (69 percent and 70 percent, respectively).³⁰ Although smaller surveys indicate a higher prevalence of overweight and obesity in American Indians, Alaska Natives, and Pacific Islander Americans and a lower prevalence in Asian Americans compared to the general population, the number surveyed in NHANES III was too small to reliably report prevalence comparisons of overweight and obesity for these populations.³⁴

FIGURE 6: AGE-ADJUSTED PREVALENCE OF OVERWEIGHT OR OBESITY IN SELECTED GROUPS (NHANES III, 1988–1994)



Source: Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS), National Health and Nutrition Examination Survey (NHANES)

Racial and ethnic disparities in overweight may also occur in children and adolescents. Data for youth from NHANES III showed a similar pattern to that seen among adults. Mexican American boys tended to have a higher prevalence of overweight than non-Hispanic black and non-Hispanic white boys. Non-Hispanic black girls tended to have a higher prevalence of overweight compared to non-Hispanic white and Mexican American girls. The National Heart, Lung, and Blood Institute Growth and Health Study on overweight in children found a higher mean BMI for black girls aged 9 and 10 years, compared to white girls of the same ages. This racial difference in BMI widened and was even greater at age 19.36

In addition to racial and ethnic and gender disparities, the prevalence of overweight and obesity also varies by age. Among both men and women, the prevalence of overweight and obesity increases with advancing age until the sixth decade, after which it starts to decline.³⁰

SOCIOECONOMIC STATUS

Disparities in the prevalence of overweight and obesity also exist based on socioeconomic status. For all racial and ethnic groups combined, women of lower socioeconomic status (income ≤ 130 percent of poverty threshold) are approxi-

mately 50 percent more likely to be obese than those with higher socioeconomic status (income > 130 percent of poverty threshold). Men are about equally likely to be obese whether they are in a low or high socioeconomic group.³⁷

Among children, the relationship between socioeconomic status and overweight in girls is weaker than it is in women; that is, girls from lower income families have not consistently been found to be overweight compared to girls from higher income families. Among Mexican American and non-Hispanic black children and adolescents, family income does not reliably predict overweight prevalence. However, non-Hispanic white adolescents from lower income families experience a greater prevalence of overweight than those from higher income families.¹⁵

HEALTH BENEFITS OF WEIGHT LOSS

The recommendations to treat overweight and obesity are based on two rationales. First, overweight and obesity are associated with an increased risk of disease and death, as previously discussed.^{3,16,18} Second, randomized controlled trials have shown that weight loss (as modest as 5 to 15 percent of excess total body weight) reduces the risk factors for at least some diseases, particularly cardiovascular disease, in the short term. Weight loss results in lower blood pressure, lower blood sugar, and improved lipid levels.³⁸ While few published studies have examined the link between weight loss and reduced disease or death in the long-term,³⁹ current data as well as scientific plausibility suggest this link.

Studies have shown that reducing risk factors for heart disease, such as blood pressure and blood cholesterol levels, lowers death rates from heart disease and stroke. Therefore, it is highly probable that weight loss that reduces these risk factors will reduce the number of deaths from heart disease and stroke. Trials examining the direct effects of weight loss on disease and death are currently under way. For example, one trial shows that weight loss, a healthful diet, and exercise prevent the development of type 2 diabetes among persons who are overweight or obese. The recently completed Diabetes Prevention Program from NIH also confirmed significant reductions in the risk for developing type 2 diabetes among obese subjects with impaired glucose tolerance through similar lifestyle interventions.

Filed 02/15/2008 Page 16 of 39
SECTION 2:

Posing Questions and Developing Strategies

Current knowledge is clear on many issues: the prevalence of overweight and obesity is high, and that of obesity is increasing rapidly; adolescents who are overweight are at high risk of becoming overweight or obese adults; overweight and obesity increase the risk for serious diseases such as type 2 diabetes, hypertension, and high blood cholesterol; and overweight and obesity are associated with premature death and disability. It is also known that a healthy diet and adequate physical activity aid in maintaining a healthy weight and, among overweight or obese persons, can promote weight loss.

Knowledge is less clear, however, on some very important questions. How can overweight and obesity be prevented? What are the most effective prevention and treatment strategies? How can the environment be modified to promote healthier eating and increased physical activity? Determining the answers to these questions demands a national public health response. Assembling the components of this response has begun.

DEVELOPING A PUBLIC HEALTH RESPONSE

In December 2000, the Surgeon General hosted a public Listening Session on overweight and obesity. The meeting—Toward a National Action Plan on Overweight and Obesity: The Surgeon General's Initiative—began a developmental process that led to this *Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity*. A menu of important activities has been assembled from comments received during the Surgeon General's Listening Session, a public comment period, and the National Nutrition Summit. The menu, which is presented in the following section, highlights areas that received significant attention during one or more of these events. Although not meant to be prescriptive, the menu should establish useful starting points as individuals and groups focus their own skills, creativity, and inspiration on the national epidemic of overweight and obesity.

The discussions at the Surgeon General's Listening Session centered on activities and interventions in five key settings: families and communities, schools, health care, media and communications, and worksites. The key actions discussed are presented for each of these settings. Many of these actions overlap the different settings and can be applied in several or all environments.

CARE To Address Overweight and Obesity

The key actions are organized by setting in a framework called CARE: Communication, Action, and Research and Evaluation.

Communication: Provision of information and tools to motivate and empower decision makers at the governmental, organizational, community, family, and individual levels who will create change toward the prevention and decrease of overweight and obesity.

Action: Interventions and activities that assist decision makers in preventing and decreasing overweight and obesity, individually or collectively.

Research and Evaluation: Investigations to better understand the causes of overweight and obesity, to assess the effectiveness of interventions, and to develop new communication and action strategies.

Within the CARE framework, effective actions must occur at multiple levels. Obviously, individual behavioral change lies at the core of all strategies to reduce overweight and obesity. Successful efforts, however, must focus not only on individual behavioral change, but also on group influences, institutional and community influences, and public policy. Actions to reduce overweight and obesity will fail without this multidimensional approach. Individual behavioral change can occur only in a supportive environment with accessible and affordable healthy food choices and opportunities for regular physical activity. Furthermore, actions aimed exclusively at individual behavioral change, while not considering social, cultural, economic, and environmental influences, are likely to reinforce attitudes of stigmatization against the overweight and obese.

SETTING 1: Families and Communities

Families and communities lie at the foundation of the solution to the problems of overweight and obesity. Family members can share their own knowledge and

habits regarding a healthy diet and physical activity with their children, friends, and other community members. Emphasis should be placed on family and community opportunities for communication, education, and peer support surrounding the maintenance of healthy dietary choices and physical activity patterns.

OMMUNICATION

- Raise consumer awareness about the effect of being overweight on overall health.
- Inform community leaders about the importance of developing healthy communities.
- Highlight programs that support healthful food and physical activity choices to community decision makers.
- Raise policy makers' awareness of the need to develop social and environmental policy that would help communities and families be more physically active and consume a healthier diet.
- Educate individuals, families, and communities about healthy dietary patterns and regular physical activity, based on the *Dietary Guidelines for Ameri*cans.
- Educate parents about the need to serve as good role models by practicing healthy eating habits and engaging in regular physical activity in order to instill lifelong healthy habits in their children.
- Raise consumer awareness about reasonable food and beverage portion sizes.
- Educate expectant parents and other community members about the potentially protective effect of breastfeeding against the development of obesity.

ACTION

- Form community coalitions to support the development of increased opportunities to engage in leisure time physical activity and to encourage food outlets to increase availability of low-calorie, nutritious food items.
- Encourage the food industry to provide reasonable food and beverage portion sizes.
- Increase availability of nutrition information for foods eaten and prepared away from home.

- Create more community-based obesity prevention and treatment programs for children and adults.
- Empower families to manage weight and health through skill building in parenting, meal planning, and behavioral management.
- Expand efforts to encourage healthy eating patterns, consistent with the *Dietary Guidelines for Americans*, by nutrition assistance recipients.
- Provide demonstration grants to address the lack of access to and availability of healthy affordable foods in inner cities.
- Promote healthful dietary patterns, including consumption of at least five servings of fruits and vegetables a day.
- Create community environments that promote and support breastfeeding.
- Decrease time spent watching television and in similar sedentary behaviors by children and their families.
- Provide demonstration grants to address the lack of public access to safe and supervised physical activity.
- Create and implement public policy related to the provision of safe and accessible sidewalks, walking and bicycle paths, and stairs.

RESEARCH AND EVALUATION

- Conduct research on obesity prevention and reduction to confirm their effects on improving health outcomes.
- Determine the root causes, behaviors, and social and ecological factors leading to obesity and how such forces vary by race and ethnicity, gender, and socioeconomic status.
- Assess the factors contributing to the disproportionate burden of overweight and obesity in low-income and minority racial and ethnic populations.
- Develop and evaluate preventive interventions that target infants and children, especially those who are at high risk of becoming obese.
- Coordinate research activities to refine risk assessment, to enhance obesity prevention, and to support appropriate consumer messages and education.
- Study the cost-effectiveness of community-directed strategies designed to prevent the onset of overweight and obesity.

- Conduct behavioral research to identify how to motivate people to increase and maintain physical activity and make healthier food choices.
- Evaluate the feasibility of incentives that support healthful dietary and physical activity patterns.
- Identify techniques that can foster community motivation to reduce overweight and obesity.
- Examine the marketing practices of the fast food industry and the factors determining construction of new food outlets.

SETTING 2: SCHOOLS

Schools are identified as a key setting for public health strategies to prevent and decrease the prevalence of overweight and obesity. Most children spend a large portion of time in school. Schools provide many opportunities to engage children in healthy eating and physical activity and to reinforce healthy diet and physical activity messages. Public health approaches in schools should extend beyond health and physical education to include school policy, the school physical and social environment, and links between schools and families and communities. Schools and communities that are interested in reducing overweight among the young people they serve can consider options listed below. Decisions about which options to select should be made at the local level.

COMMUNICATION

- Build awareness among teachers, food service staff, coaches, nurses, and other school staff about the contribution of proper nutrition and physical activity to the maintenance of lifelong healthy weight.
- Educate teachers, staff, and parents about the importance of school physical activity and nutrition programs and policies.
- Educate parents, teachers, coaches, staff, and other adults in the community about the importance they hold as role models for children, and teach them how to be models for healthy eating and regular physical activity.
- Educate students, teachers, staff, and parents about the importance of body size acceptance and the dangers of unhealthy weight control practices.

 Develop sensitivity of staff to the problems encountered by the overweight child.

A CTION

- Provide age-appropriate and culturally sensitive instruction in health education that helps students develop the knowledge, attitudes, skills, and behaviors to adopt, maintain, and enjoy healthy eating habits and a physically active lifestyle.
- Ensure that meals offered through the school breakfast and lunch programs meet nutrition standards.
- Adopt policies ensuring that all foods and beverages available on school campuses and at school events contribute toward eating patterns that are consistent with the *Dietary Guidelines for Americans*.
- Provide food options that are low in fat, calories, and added sugars, such as fruits, vegetables, whole grains, and low-fat or nonfat dairy foods.
- Ensure that healthy snacks and foods are provided in vending machines, school stores, and other venues within the school's control.
- Prohibit student access to vending machines, school stores, and other venues that compete with healthy school meals in elementary schools and restrict access in middle, junior, and high schools.
- Provide an adequate amount of time for students to eat school meals, and schedule lunch periods at reasonable hours around midday.
- Provide all children, from prekindergarten through grade 12, with quality daily physical education that helps develop the knowledge, attitudes, skills, behaviors, and confidence needed to be physically active for life.
- Provide daily recess periods for elementary school students, featuring time for unstructured but supervised play.
- Provide extracurricular physical activity programs, especially inclusive intramural programs and physical activity clubs.
- Encourage the use of school facilities for physical activity programs offered by the school and/or community-based organizations outside of school hours.

RESEARCH AND EVALUATION

- Conduct research on the relationship of healthy eating and physical activity to student health, learning, attendance, classroom behavior, violence, and other social outcomes.
- Evaluate school-based behavioral health interventions for the prevention of overweight in children.
- Develop an ongoing, systematic process to assess the school physical activity and nutrition environment, and plan, implement, and monitor improvements.
- Conduct research to study the effect of school policies such as food services and physical activity curricula on overweight in children and adolescents.
- Evaluate the financial and health impact of school contracts with vendors of high-calorie foods and beverages with minimal nutritional value.

SETTING 3: HEALTH CARE

The health care system provides a powerful setting for interventions aimed at reducing the prevalence of overweight and obesity and their consequences. A majority of Americans interact with the health care system at least once during any given year. Recommendations by pediatric and adult health care providers can be influential in patient dietary choices and physical activity patterns. In collaboration with schools and worksites, health care providers and institutions can reinforce the adoption and maintenance of healthy lifestyle behaviors. Health care providers also can serve as effective public policy advocates and further catalyze intervention efforts in the family and community and in the media and communications settings.

OMMUNICATION

• Inform health care providers and administrators of the tremendous burden of overweight and obesity on the health care system in terms of mortality, morbidity, and cost.

- Inform and educate the health care community about the importance of healthy eating, consistent with the *Dietary Guidelines for Americans*, and physical activity and fitness for the promotion of health.
- Educate health care providers and administrators to identify and reduce the barriers involving patients' lack of access to effective nutrition and physical activity interventions.
- Inform and educate the health care community about assessment of weight status and the risk of inappropriate weight change.
- Educate health care providers on effective ways to promote and support breastfeeding.

A CTION

- Train health care providers and health profession students in effective prevention and treatment techniques for overweight and obesity.
- Encourage partnerships between health care providers, schools, faith-based groups, and other community organizations in prevention efforts targeted at social and environmental causes of overweight and obesity.
- Establish a dialogue to consider classifying obesity as a disease category for reimbursement coding.
- Explore mechanisms that will partially or fully cover reimbursement or include as a member benefit health care services associated with weight management, including nutrition education and physical activity programs.

RESEARCH AND EVALUATION

- Develop effective preventive and therapeutic programs for obesity.
- Study the effect of weight reduction programs on health outcomes.
- Analyze the cost-effectiveness data on clinical obesity prevention and treatment efforts and conduct further research where the data are inconclusive.
- Promote research on the maintenance of weight loss.
- Promote research on breastfeeding and the prevention of obesity.
- Review and evaluate the reimbursement policies of public and private health insurance providers regarding overweight and obesity prevention and treatment efforts.

SETTING 4: MEDIA AND COMMUNICATIONS

The media can provide essential functions in overweight and obesity prevention efforts. From a public education and social marketing standpoint, the media can disseminate health messages and display healthy behaviors aimed at changing dietary habits and exercise patterns. In addition, the media can provide a powerful forum for community members who are addressing the social and environmental influences on dietary and physical activity patterns.

COMMUNICATION

- Emphasize to media professionals that the primary concern of overweight and obesity is one of health rather than appearance.
- Emphasize to media professionals the disproportionate burden of overweight and obesity in low-income and racial and ethnic minority populations and the need for culturally sensitive health messages.
- Communicate the importance of prevention of overweight through balancing food intake with physical activity at all ages.
- Promote the recognition of inappropriate weight change.
- Build awareness of the importance of social and environmental influences on making appropriate diet and physical activity choices.
- Provide professional education for media professionals on policy areas related to diet and physical activity.
- Emphasize to media professionals the need to develop uniform health messages about physical activity and nutrition that are consistent with the *Dietary Guidelines for Americans*.

ACTION

- Conduct a national campaign to foster public awareness of the health benefits of regular physical activity, healthful dietary choices, and maintaining a healthy weight, based on the *Dietary Guidelines for Americans*.
- Encourage truthful and reasonable consumer goals for weight loss programs and weight management products.

- Incorporate messages about proper nutrition, including eating at least five servings of fruits and vegetables a day, and regular physical activity in youthoriented TV programming.
- Train nutrition and exercise scientists and specialists in media advocacy skills that will empower them to disseminate their knowledge to a broad audience.
- Encourage community-based advertising campaigns to balance messages that may encourage consumption of excess calories and inactivity generated by fast food industries and by industries that promote sedentary behaviors.
- Encourage media professionals to utilize actors' influences as role models to demonstrate eating and physical activity lifestyles for health rather than for appearance.
- Encourage media professionals to employ actors of diverse sizes.

RESEARCH AND EVALUATION

- Evaluate the impact of community media advocacy campaigns designed to achieve public policy and health-related goals.
- Conduct consumer research to ensure that media messages are positive, realistic, relevant, consistent, and achievable.
- Increase research on the effects of popular media images of ideal body types and their potential health impact, particularly on young women.

SETTING 5: WORKSITES

More than 100 million Americans spend the majority of their day at a worksite. While at work, employees are often aggregated within systems for communication, education, and peer support. Thus, worksites provide many opportunities to reinforce the adoption and maintenance of healthy lifestyle behaviors. Public health approaches in worksites should extend beyond health education and awareness to include worksite policies, the physical and social environments of worksites, and their links with the family and community setting.

COMMUNICATION

- Inform employers of the direct and indirect costs of obesity.
- Communicate to employers the return-on-investment (ROI) data for worksite obesity prevention and treatment strategies.

ACTION

- Change workflow patterns, including flexible work hours, to create opportunities for regular physical activity during the workday.
- Provide protected time for lunch, and ensure that healthy food options are available.
- Establish worksite exercise facilities or create incentives for employees to join local fitness centers.
- Create incentives for workers to achieve and maintain a healthy body weight.
- Encourage employers to require weight management and physical activity counseling as a member benefit in health insurance contracts.
- Create work environments that promote and support breastfeeding.
- Explore ways to create Federal worksite programs promoting healthy eating and physical activity that will set an example to the private sector.

RESEARCH AND EVALUATION

- Evaluate best practices in worksite overweight and obesity prevention and treatment efforts, and disseminate results of studies widely.
- Evaluate economic data examining worksite obesity prevention and treatment efforts.
- Conduct controlled worksite studies of the impact of overweight and obesity management programs on worker productivity and absenteeism.

Filed 02/15/2008 Page 22 of 39

Section 3:

The Power of People and Ideas

Public health efforts are carried by the force of ideas and by the power of commitment. Healthy People 2010 identifies goals to improve the country's health status, including reducing the prevalence of overweight and obesity. This Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity addresses the Healthy People 2010 objectives to reduce the prevalence of overweight and obesity and presents many ideas by which this can be done. Translating these ideas into meaningful action will require a great commitment. We must collectively build on existing successful programs in both the public and private sectors, identify current gaps in action, and develop and initiate actions to fill those gaps. Public-private working groups should be formed around key themes or around the major settings in which obesity prevention and treatment efforts need to take place. While the magnitude of the problem is great, the range of potential solutions is even greater. The design of successful interventions and actions for prevention and management of overweight and obesity will require the careful attention of many individuals and organizations working together through multiple spheres of influence.

INDIVIDUALS

Individuals lie at the foundation of the solution to the problems of overweight and obesity. Individuals can share their own knowledge and habits regarding a healthy diet and physical activity with their children, other family members, friends, and co-workers. Through frank dialogue regarding the methods, challenges, and benefits of adopting a healthy lifestyle, individuals can make the effort to combat the obesity epidemic both personal and relevant.

ORGANIZATIONS

Organizations represent individuals who have common goals and purposes. Organizations can initiate discussions on obesity and overweight within their membership and can establish weight and lifestyle goals. Organizations can develop programs that educate members on food choices and appropriate levels of physical

activity and engage members in these healthy habits. Using their links to and influence within the broader community, organizations can share their experiences in weight management and thus serve as an important public resource.

INDUSTRY

Industry has a vital role in the prevention of overweight and obesity. Through the production and distribution of food and other consumer products, industry exerts a tremendous impact on the nutritional quality of the food we eat and the extent of physical activity in which we engage. Industry can use that leverage to create and sustain an environment that encourages individuals to achieve and maintain a healthy or healthier body weight.

COMMUNITIES

Communities consist of multiple components, including individuals, faith-based and other community organizations, worksites, and governments. A forum should be provided in which all community members can discuss the scope of the problem of overweight and obesity within the community. Also, the nature and adequacy of available resources for public education and treatment, as well as current and future policies and programs to reduce the burden of overweight and obesity within the community, must be addressed. Clearly, the discussions and the strategies adopted will vary depending on the prevalence of obesity and overweight within each community.

GOVERNMENT

Local governments can work together with organizations and communities to facilitate goals for reducing overweight and obesity. Local governments can assist with providing services to increase physical activity and improve nutritional intake. State, Tribal, and local governments can collaborate more with Federal nutrition assistance programs that provide services promoting healthy eating and physical activity. States can form task forces, steering committees, or advisory committees and can also develop State strategic plans. State and national governments can provide funding for research on the effects of interventions on overweight and obesity prevalence, prevention, and treatment, and on trends in diet and exercise

among at-risk populations. Governments can also provide support for public education, public awareness campaigns, and treatment services. Finally, governments can create and promote policies that promote an environment in which healthy dietary and physical activity options are readily accessible.

CREATING NATIONAL ACTION

Interventions and actions in the fundamental areas of the CARE approach should catalyze a process of national, State, and local action to address overweight and obesity. While strategies and action steps will vary, all who take action should acknowledge and embrace the following principles:

- Actions by diversified and cooperative groups are desirable. Working groups
 may form around settings or around crosscutting themes, as appropriate, to
 best leverage their talents and resources against overweight and obesity.
 Partnerships among all levels of government; public and private national,
 State, Tribal, and local organizations; and faith-based and other community
 groups will increase the likelihood that true gaps in action will be addressed.
 Partnerships also may foster learning, sharing of resources, division of labor, and consistency in the message to the public. Additionally, they may
 enhance media prominence and the social credibility of actions to address
 overweight and obesity.
- Actions require vigorous, dedicated commitment. The social, environmental, and behavioral factors responsible for the epidemic of overweight and obesity are firmly entrenched in our society. Identifying and dislodging these factors will require deliberate, persistent action and a degree of patience.
- Actions should strive to help all Americans maintain a healthy or healthier weight through balancing caloric intake and energy expenditure. Actions should focus at multiple levels, targeting the environment, behavior change, and policy.
- Actions should be carefully planned. The choice of actions should be based
 on the relative feasibility, effectiveness, and suitability of all potential actions, and all partners should have a clearly defined role in the action.

- Actions should be sensitive to the needs of minority populations and to the social stigmatization that can surround overweight and obesity.
- Actions and their outcomes should be evaluated. While implementing a
 system to monitor outcomes should not stand as a barrier to action, groups
 that are able should monitor and document the short-term and long-term
 effects of the actions they take. This type of tracking provides important
 information for the next round of actions and increases the likelihood of
 success. Developing a concrete evaluation plan early may help focus the
 goals for action.

SUSTAINING NATIONAL ACTION

Effectiveness of the public health response to overweight and obesity requires strong leadership, regular monitoring, and committed support of all—government; industry; public, private, and professional organizations; communities; schools; families; and individuals. These features will ensure sustained action, productive collaboration, and ongoing progress toward the vision of this *Call To Action*.

LEADERSHIP

A network of leadership across the country needs to be established to ensure that actions are employed in the appropriate settings nationwide. This network should be structured at the organizational, industrial, State, and community levels. The creation of a public-private partnership in the form of a national steering committee could provide an overarching perspective and a more centralized leadership to such efforts. A dialogue among all these spheres of leadership is essential. Several key functions of this leadership structure are described in the following section.

Monitoring

The effectiveness of a CARE approach to overweight and obesity must be assessed at regular intervals. Monitoring should include gathering new information on overweight and obesity as well as reporting on the status of current interventions.

Information Gathering

- Update on the biological, epidemiological, and psychological aspects of obesity and overweight.
- Review of surveillance data systems to track overweight and obesity.
- Update on the latest behavioral and pharmacological interventions for overweight and obesity.
- Discussion of new ideas and goals for continued national activity.

Reporting

- Reporting on progress based on measurable objectives, such as those outlined in *Healthy People 2010*.
- Discussion of the progress achieved through actions undertaken within the various settings.
- Reporting on the status of current policies, programs, and interventions.
- Creation and dissemination of a library of best practices based on evidencebased programs.
- Recognition of exemplary intervention programs, for example, through an awards program.

Monitoring will ensure that all members of the various settings can communicate their ideas and strategies. Monitoring will allow planners to see which objectives are reached or exceeded as well as those that fall short of expectations.

PROMOTION

In addition to strong leadership and regular evaluation, a successful public health effort requires active promotion. Continuous public education on the magnitude of the problem of overweight and obesity will reinforce the goals of the national effort and will encourage public participation. Therefore, the national action to combat overweight and obesity should:

- Foster a consistent message to the public regarding the risks of overweight and obesity as well as the mechanisms by which a person can adopt a healthy lifestyle.
- Target high-risk groups for education on overweight and obesity.

- Promote interventions that address disparities in the prevalence of overweight and obesity.
- Seek to improve the general sensitivity to the social stigma of overweight and obesity.

COMMITTED GOVERNMENT SUPPORT

Local, State, Tribal, and national governments have previously declared their support of efforts to maintain and improve America's health. Such governmental backing may be enhanced through the following:

- Creation of laws and policies that support a healthy physical and nutritional environment for the public.
- Allocation of resources to both government and private organizations to carry out national action to prevent and decrease overweight and obesity.
- Provision of authority to specific Federal and State agencies to enforce policies aimed at reducing overweight and obesity.

Ongoing Dialogue

At a minimum, a national steering committee should convene an annual meeting modeled after the Surgeon General's Listening Session. This event would provide leaders with a useful forum for information exchange and enhance their abilities to carry out the functions listed above.

Filed 02/15/2008 Page 25 of 39 SECTION 4: Vision for the Future

This Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity underscores the tremendous health impact that overweight and obesity have on the United States. Through widespread action on the part of all Americans, this Call To Action aims to catalyze a process that will reduce the prevalence of overweight and obesity on a nationwide scale. Without support and investment from a broad array of public and private partners, these efforts will not succeed. With such support, however, there exist few limitations on the potential of this effort to improve the health of individuals, families, communities, and, ultimately, the Nation as a whole.

SURGEON GENERAL'S PRIORITIES FOR ACTION

The previously discussed CARE framework presents a menu of important activities for the prevention and treatment of overweight and obesity. Building from this menu, the Surgeon General identifies the following 15 activities as national priorities for immediate action. Individuals, families, communities, schools, worksites, health care, media, industry, organizations, and government must determine their role and take action to prevent and decrease overweight and obesity.

COMMUNICATION

The Nation must take an informed, sensitive approach to communicate with and educate the American people about health issues related to overweight and obesity. Everyone must work together to:

- Change the perception of overweight and obesity at all ages. The primary concern should be one of health and not appearance.
- Educate all expectant parents about the many benefits of breastfeeding.
 - Breastfed infants may be less likely to become overweight as they grow older.
 - Mothers who breastfeed may return to pre-pregnancy weight more quickly.
- Educate health care providers and health profession students in the prevention and treatment of overweight and obesity across the lifespan.

 Provide culturally appropriate education in schools and communities about healthy eating habits and regular physical activity, based on the *Dietary Guidelines for Americans*, for people of all ages. Emphasize the consumer's role in making wise food and physical activity choices.

ACTION

The Nation must take action to assist Americans in balancing healthful eating with regular physical activity. Individuals and groups across all settings must work in concert to:

- Ensure daily, quality physical education in all school grades. Such education can develop the knowledge, attitudes, skills, behaviors, and confidence needed to be physically active for life.
- Reduce time spent watching television and in other similar sedentary behaviors.
- Build physical activity into regular routines and playtime for children and their families. Ensure that adults get at least 30 minutes of moderate physical activity on most days of the week. Children should aim for at least 60 minutes.
- Create more opportunities for physical activity at worksites. Encourage all
 employers to make facilities and opportunities available for physical activity for all employees.
- Make community facilities available and accessible for physical activity for all people, including the elderly.
- Promote healthier food choices, including at least five servings of fruits and vegetables each day, and reasonable portion sizes at home, in schools, at worksites, and in communities.
- Ensure that schools provide healthful foods and beverages on school campuses and at school events by:
 - Enforcing existing U.S. Department of Agriculture regulations that prohibit serving foods of minimal nutritional value during mealtimes in school food service areas, including in vending machines.

- Adopting policies specifying that all foods and beverages available at school contribute toward eating patterns that are consistent with the *Dietary Guidelines for Americans*.
- Providing more food options that are low in fat, calories, and added sugars such as fruits, vegetables, whole grains, and low-fat or nonfat dairy foods.
- Reducing access to foods high in fat, calories, and added sugars and to excessive portion sizes.
- Create mechanisms for appropriate reimbursement for the prevention and treatment of overweight and obesity.

RESEARCH AND EVALUATION

The Nation must invest in research that improves our understanding of the causes, prevention, and treatment of overweight and obesity. A concerted effort should be made to:

- Increase research on behavioral and environmental causes of overweight and obesity.
- Increase research and evaluation on prevention and treatment interventions for overweight and obesity, and develop and disseminate best practice guidelines.
- Increase research on disparities in the prevalence of overweight and obesity
 among racial and ethnic, gender, socioeconomic, and age groups, and use
 this research to identify effective and culturally appropriate interventions.

CONCLUSION

This *Call To Action* is for all who can have an impact on overweight and obesity in the United States to take action to create a future where:

- It is widely recognized that overweight and obesity can reduce the length and quality of life.
- The etiology of this complex problem of overweight and obesity is better understood.

- Effective and practical prevention and treatment are widely available and integrated in health care systems.
- Environments have been modified to promote healthy eating and increased physical activity.
- Disparities in overweight and obesity prevalence based on race and ethnicity, socioeconomic status, gender, and age are eliminated.
- The health consequences of overweight and obesity are reduced.
- The social stigmatism associated with overweight and obesity is eradicated.

This vision should be approached vigorously and optimistically but with patience. There is no simple or quick answer to this multifaceted challenge. This *Surgeon General's Call To Action To Prevent and Decrease Overweight and Obesity* calls upon individuals, families, communities, schools, worksites, organizations, government, and the media to work together to build solutions that will bring better health to everyone in this country. Working together, we can make this vision become a reality.

Filed 02/15/2008

Page 27 of 39

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Filed 02/15/2008 Page 29 of 39 Acknowledgments

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Filed 02/15/2008 Page 31 of 39

APPENDIX A:

Examples of Federal Programs and Initiatives

Programs on overweight and obesity span multiple departments, offices, and agencies in the Federal Government and promote valuable research and action in various settings. These programs are amplified by State, Tribal, local, and private-sector activities. Some examples of Federal initiatives on overweight and obesity, and the programs that support them, are listed below. For more information on a number of these programs, please see appendix B.

SETTING 1: FAMILIES AND COMMUNITIES

- The Centers for Disease Control and Prevention (CDC) has a community planning tool called the *Planned Approach to Community Health (PATCH)*. This tool can be valuable in the process of developing and sustaining action.
- The Federal Highway Administration, the Environmental Protection Agency, and the Georgia Department of Transportation have developed *Strategies for Metropolitan Atlanta's Regional Transportation and Air Quality*, a document that provides a framework for assessing which factors of land use and transportation investment policies have the greatest potential to reduce the level of automobile dependence, which may consequently increase walking and bicycling activities while promoting the economic and environmental health of the Atlanta metropolitan region.
- The Head Start Bureau of the Administration for Children and Families, in conjunction with members of the community and various Federal agencies, will convene a focus group in fall 2002 to identify issues, effective practices, and recommendations addressing overweight in children of the Head Start Program.
- The Head Start Bureau has published a *Training Guide for the Head Start Learning Community: Enhancing Health in the Head Start Workplace*. The guide addresses the importance of health in the workplace and presents health

- promotion principles and activities that can be applied to a variety of workplace health issues, including achieving and maintaining a healthy weight.
- The Health Resources and Services Administration (HRSA) has sponsored Statewide Partnerships in Women's Health that have begun a new prevention initiative entitled WISEWOMAN. Three Statewide Partnerships in Women's Health grantees (Alaska, North Carolina, and Vermont) have WISEWOMAN programs in their States. These grantees are encouraged to collaborate with the WISEWOMAN programs in their States and with other community-based partners to support cardiovascular screenings for women aged 40 to 64 years who then receive nutrition counseling and physical activity support.
- Under the Healthy People 2010 initiative, the Department of Health and Human Services (HHS) has produced the document *Healthy People in Healthy Communities: A Community Planning Guide Using Healthy People 2010.* This document is a guide to developing an action plan through building community coalitions, creating a vision, measuring results, and creating partnerships. It outlines strategies to help start community activities.
- HHS sponsored the development of a *Healthy People 2010 Toolkit* to provide guidance, technical tools, and resources to groups as they develop and sustain a successful plan of action. The *Toolkit* is organized around common elements of health planning and improvement and provides useful tips for getting started.
- HHS has recently released a *Blueprint for Action on Breastfeeding*. The *Blueprint for Action*, which was developed by health and scientific experts from 14 Federal agencies and 23 health care professional organizations, offers action steps for the health care system, families, the community, researchers, and the workplace to better focus attention on the importance of breastfeeding.
- HHS, the U.S. Department of Agriculture (USDA) and other organizations
 have collaborated to form the United States Breastfeeding Committee. They
 have developed *Breastfeeding in the United States: A National Agenda*, which
 is a strategic plan to protect, promote, and support breastfeeding.

- The Indian Health Service and Head Start Bureau have partnered in the development of an initiative, Healthy Children, Healthy Families, and Healthy Communities: A Focus on Diabetes and Obesity Prevention, which has focused on obesity and diabetes prevention activities for Head Start children, families, staff, and communities.
- The National Institutes of Health (NIH) Pathways research fosters culturally appropriate healthy eating practices and increased physical activity among American Indian children, their families, food service staff, and physical education and classroom teachers.
- NIH and the National Recreation and Park Association have developed the Hearts N' Parks program, which will create national dissemination magnet sites for implementing activities encouraging healthy eating and physical activity.
- NIH has developed a health awareness campaign called Sisters Together:
 Move More, Eat Better to encourage African American women in Boston to
 maintain or achieve a healthier weight by increasing their physical activity
 and eating healthy foods. NIH is currently expanding this program to other
 sites.
- The Office for American Indian, Alaska Native, and Native Hawaiian Programs has developed the Wisdom Steps Health Promotion Program for Elders, a partnership between the Tribes and Minnesota's State Unit on Aging. The program promotes health awareness, with major emphasis on assisting elders in weight loss, participation in exercise programs, improvement of diet, and smoking cessation.
- The Office on Women's Health has developed the Girls and Obesity Initiative, serving to identify existing government obesity programs and to adapt these programs toward gender-specific guidance for girls.
- USDA's Cooperative State Research, Education, and Extension Service (CSREES) has developed a nationwide project, Reversing Childhood Obesity Trends: Helping Children Achieve Healthy Weights. This project will achieve its goals through the integration of research, education, and innovative approaches to help children achieve healthy weights. The project will test a number of program interventions designed to reduce the prevalence of

- childhood overweight and obesity in various populations. Both quantitative and qualitative methodologies will be employed in determining the most appropriate and effective program intervention for a specific population.
- CSREES also funds WIN the Rockies (Wellness IN the Rockies), which
 seeks to improve attitudes and behaviors about food, physical activity, and
 body image among rural residents of Idaho, Montana, and Wyoming in order to reverse the rising tide of obesity. Interventions will be community
 based and will target youth, limited-resource audiences, and overweight or
 obese adults.
- The Women, Infants, and Children (WIC) Farmer's Market Nutrition Program was established by Congress to provide fresh and nutritious foods from farmers' markets to low-income families participating in the WIC program.

SETTING 2: SCHOOLS

- The Assistant Secretary for Health, the Assistant Secretary of Elementary and Secondary Education, and USDA's Under Secretary for Food, Nutrition, and Consumer Services co-chair a Federal Interagency Committee on School Health that serves to integrate efforts across three Cabinet departments to improve the health and education of young people, including efforts to prevent and decrease obesity.
- CDC currently supports 20 State education agencies for coordinated school
 health programs to reduce the following chronic disease risk factors: tobacco use, poor eating habits, physical activity, and obesity. CDC also has
 developed guidelines for school health programs based on a review of published research and input from academic experts.
- School Health Index for Physical Activity and Healthy Eating: A Self Assessment & Planning Guide, is a guide developed by CDC that enables schools to identify strengths and weaknesses of their physical activity and nutrition policies and programs; develop an action plan for improving student health; and involve teachers, parents, students, and the community in improving school services.

- CDC and USDA are developing a mentoring curriculum to promote nutrition and physical activity in 11- to 18-year-old African American males in an effort to address racial disparities in nutrition and physical activity.
- CDC, the President's Council on Physical Fitness and Sports (PCPFS), and
 the Department of Education have developed a report, *Promoting Better Health for Young People Through Physical Activity and Sports*, in which
 they describe strategies to increase the number of youth engaging in physical activity.
- PCPFS has developed the President's Challenge Physical Activity and Fitness Awards Program, incorporating the Presidential, National, Participant, and Health Fitness Awards, and for the first time this year, the Presidential Active Lifestyle Award; the State Champion Award; the National School Demonstration Program; and the Presidential Sports Award Program as means of encouraging individual children and schools to adopt and maintain an active, fit, and healthy lifestyle.
- USDA has launched efforts to foster healthy school environments that support proper nutrition and the development of healthful eating habits, including re-emphasizing regulations that prohibit serving foods of minimal nutritional value in the food service area during meal periods.
- USDA's Team Nutrition includes a multitude of nutrition education materials for children ranging from prekindergarten through high school that support concepts to maintain a healthy weight. Team Nutrition provides grants to States promoting the Federal *Dietary Guidelines for Americans*, healthy food choices, and physical activity.
- USDA's Team Nutrition resources include a Food and Nutrition Service's "action kit," *Changing the Scene: Improving the School Nutrition Environment*, which can be used at the State and local levels to educate decision makers about the role school environments play in helping students meet the goals of the *Dietary Guidelines for Americans*.

SETTING 3: HEALTH CARE

- The Agency for Healthcare Research and Quality is supporting the U.S.
 Preventive Services Task Force's update to the 1996 *Guide to Clinical Preventive Services* chapter on screening for obesity. The report will be expanded to address screening and counseling for overweight and obesity and will assess the effectiveness of primary care-based interventions to prevent or treat obesity.
- CDC has been active in leading discussions about reimbursement, or inclusion as a member benefit, for services relating to the prevention and treatment of overweight and obesity.
- CDC is focusing on the prevention of pediatric overweight in the primary care setting.
- The Department of Defense has developed the LEAN Program, a healthy lifestyle model for the treatment of obesity administered in the Tripler Army Medical Center.
- HRSA and other partners including PCPFS, NIH, and CDC have developed
 Bright Futures in Practice: Physical Activity. These guidelines and tools
 emphasize health promotion, disease prevention, and early recognition of
 physical activity issues and concerns of infants, children, and adolescents.
- HRSA, in collaboration with other partners, has developed *Bright Futures in Practice: Nutrition*. These nutrition guidelines provide a thorough overview of nutrition supervision during infancy, childhood, and adolescence. The guidelines also highlight how partnerships among health professionals, families, and communities can improve the nutritional status of infants, children, and adolescents.
- HRSA sponsors a Diabetes and Hypertension Collaborative that includes nutrition and weight management education for patients in community health centers.
- NIH has developed the *Clinical Guidelines on the Identification, Evaluation, and Treatment of Overweight and Obesity in Adults: Evidence Report,* which has been formatted into various products suitable for use by physicians and other health professionals.

- NIH has collaborated with other Federal agencies to conduct and promote research on obesity and associated diseases. These studies focus on biologic and environmental determinants of human overweight and obesity, prevention strategies, and treatment modalities.
- NIH has developed a Weight-control Information Network to provide health professionals and consumers with science-based materials on obesity, weight control, and nutrition.
- HHS has charged members of NIH's National Task Force on Prevention and Treatment of Obesity to publish evidence reviews of overweight and obesity in leading medical journals to provide clinicians with the latest and most accurate information.

SETTING 4: MEDIA AND COMMUNICATIONS

- CDC is using existing surveillance systems to develop biennial reports on national, State, and local trends in the prevalence of cardiovascular disease, cancer, and diabetes; the risk factors related to these diseases; and the schoolbased programs that may reduce these risk factors.
- CDC, in conjunction with PCPFS and other private and public agencies, is
 Promoting Better Health for Young People Through Physical Activity and Sports, a document that reports on the strategies being used to involve families, school programs, recreation programs, community structural environment, and media campaigns on physical activity.
- The *PCPFS Research Digest*, a quarterly publication, synthesizes scientific information on specific topics in physical fitness, exercise science, and sports medicine for dissemination to fitness professionals and citizens.

SETTING 5: WORKSITES

• CDC has developed the Personal Energy Plan (PEP), a self-help program that promotes healthy eating and physical activity in the workplace. Worksites are encouraged to supplement the PEP self-help kits with added activities and modifications to the nutritional and physical environment.

- CDC has a Web site, Ready, Set, It's Everywhere You Go: CDC's Guide to Promoting Moderate Physical Activity, which provides resources and information on how adults can incorporate physical activity into their routines at the workplace.
- CDC has provided funding to State departments of health in Maine, Montana, New York, and North Carolina for the establishment of health promotion programs at multiple worksites. The programs are intended to formulate and implement policy and environmental changes that support increased physical activity and healthy eating.

Filed 02/15/2008 Page 35 of 39

APPENDIX B:

Federal Program Resource List

BLUEPRINT FOR ACTION ON BREASTFEEDING

Office on Women's Health

U.S. Department of Health and Human Services

200 Independence Avenue, SW., Room 730B

Washington, DC 20201

Phone: (202) 690-7650

Fax: (202) 205-2631

http://www.4woman.gov/Breastfeeding/index.htm

BRIGHT FUTURES IN PRACTICE

BRIGHT FUTURES PROJECT

HRSA/Maternal and Child Health Bureau

5600 Fishers Lane, Room 18A55

Rockville, MD 20857

Phone: (301) 443-2340

Fax: (301) 443-4842

Email: cdegraw@hrsa.gov http://www.brightfutures.org

CDC Reports and Guidelines for Overweight and Obesity

http://www.cdc.gov/health/obesity.htm

Phone: (800) 311-3435

CLINICAL GUIDELINES ON THE IDENTIFICATION, EVALUATION, AND TREATMENT OF OVERWEIGHT AND OBESITY IN ADULTS: THE

EVIDENCE REPORT

NHLBI Health Information Network

P.O. Box 30105

Bethesda, MD 20824-0105

Phone: (301) 592-8573

Fax: (301) 592-8563

http://www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm

DIETARY GUIDELINES FOR AMERICANS

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http://www.health.gov/dietaryguidelines

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http://www.nia.nih.gov/health/pubs/nasa-exercise/index.htm

EXERCISE: A VIDEO FROM THE NATIONAL INSTITUTE ON AGING

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5 A Day for Better Health

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Bethesda, MD 20892-7332

Phone: (301) 496-8520

http://dccps.nci.nih.gov/5aday/

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Office on Women's Health

U.S. Department of Health and Human Services

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Washington, DC 20201

Phone: (202) 690-7650

Fax: (202) 205-2631

http://www.4woman.gov/owh/education.htm

GUIDANCE ON HOW TO UNDERSTAND AND USE THE NUTRITION

FACTS PANEL ON FOOD LABELS

U.S. Food and Drug Administration

Center for Food Safety and Applied Nutrition

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http://www.cfsan.fda.gov/~dms/foodlab.html

Guide to Clinical Preventive Services, 2nd edition, 1996

U.S. Preventive Services Task Force

Phone: (800) 358-9295

http://www.ahrq.gov/clinic/uspstfix.htm

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http://www2.acf.dhhs.gov/programs/hsb/

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Administration on Children, Youth and Families

Administration for Children and Families

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Washington, DC 20447

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Fax: (202) 205-8436

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Office of Disease Prevention and Health Promotion

U.S. Department of Health and Human Services

200 Independence Avenue, SW., Room 738G

Washington, DC 20201

Phone: (202) 401-6295

Fax: (202) 205-9478

http://www.health.gov/healthypeople

HEALTHY PEOPLE IN HEALTHY COMMUNITIES: A COMMUNITY PLANNING GUIDE USING HEALTHY PEOPLE 2010

http://www.health.gov/healthypeople/publications/HealthyCommunities2001.

HEALTHY PEOPLE 2010 TOOLKIT

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http://www.health.gov/healthypeople/state/toolkit

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Bethesda, MD 20824

Phone: (301) 592-8573

Fax: (301) 592-8563

Email: NHLBIinfo@rover.nhlbi.nih.gov

http://www.nhlbi.nih.gov/health/prof/heart/obesity/hrt_n_pk/index.htm

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http://das.cs.amedd.army.mil/journal/J9725.HTM

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USDA Food and Nutrition Service

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http://www.fns.usda.gov/wic/content/bf/brpromo.htm

NHLBI OBESITY EDUCATION INITIATIVE

NHLBI Health Information Network

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Bethesda, MD 20824-0105

Phone: (301) 592-8573

Fax: (301) 592-8563

http://www.nhlbi.nih.gov and

http://rover.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/

Nutrition.Gov

http://www.nutrition.gov

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Surgeon General

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Email: win@info.niddk.nih.gov

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USDA Food and Nutrition Service

Child Nutrition Division

3101 Park Center Drive, Room 640

Alexandria, VA 22302

Phone: (703) 305-2590

Fax: (703) 305-2879

Email: cndinternet@fns.usda.gov

http://www.fns.usda.gov/cnd

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Office for American Indian, Alaskan Native, and Native Hawaiian

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http://www.aoa.dhhs.gov/factsheets/natams.html

DIABETES

DIABETES IN NEW YORK CITY: Public Health Burden and Disparities

TABLE OF CONTENTS

LETTER FROM THE COMMISSIONER	
EXECUTIVE SUMMARY	
INTRODUCTION	
CHAPTER 1 - PREVALENCE	1-1
CHAPTER 2 – OBESITY AND RELATED RISK FACTORS .	2-1
CHAPTER 3 – MORBIDITY: HOSPITALIZATIONS AND END-STAGE RENAL DISEASE	3-1
CHAPTER 4 - MORTALITY	4-1
CHAPTER 5 – HEALTH CARE INDICATORS	5-1
CHAPTER 6 – DIABETES DURING PREGNANCY	6-1
APPENDIX A - ABOUT THE DATA	.APXA-1
APPENDIX B – NEIGHBORHOOD TABLES AND MAPS .	.APXB-1
REFERENCES	REF-1



THE CITY OF NEW YORK

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Michael R. Bloomberg Mayor

Thomas R. Frieden, M.D., M.P.H. Commissioner

nyc.gov/health

June 2007

Dear Fellow New Yorkers:

Diabetes is epidemic in New York City. Diabetes prevalence has more than doubled over the past 10 years. More than half a million adult New Yorkers have diagnosed diabetes and an additional 200,000 have diabetes but do not yet know it. Diabetes and diabetes-associated cardiovascular disease are leading causes of death in NYC. About two-thirds of people with diabetes die from cardiovascular events. This report, Diabetes in New York City: Public Health Burden and Disparities, captures the devastating effects of the diabetes epidemic in NYC and the large disparities in its impact on different populations. This epidemic requires an effective public health response similar to that traditionally associated with communicable diseases.

Timely and complete population-level data on diabetes and its management are needed to support public health action and track its impact. Data compiled by the NYC Department of Health and Mental Hygiene (DOHMH) over the past few years, summarized in this first edition of Diabetes in New York City, are a good start but do not tell us enough about how well diabetes is being controlled. The two recent DOHMH initiatives detailed below will greatly enhance public health surveillance of the epidemic:

- As of January 15, 2006, the New York City Board of Health requires most clinical laboratories to report hemoglobin A1C test results electronically to the DOHMH. Laboratory data on A1C, a key measure of diabetes control, are being used to establish the first population-based A1C registry in the nation. The registry will enable the DOHMH to give clinicians and patients feedback and resources that can improve the quality of care and quality of life for New Yorkers with diabetes.
- The New York City Health and Nutrition Examination Survey (NYC HANES), conducted in 2004, provides data on A1C levels, blood pressure, lipids and smoking prevalence for a representative sample of New Yorkers with diabetes. For the first time, estimates on how well diabetes is controlled among NYC adults are available.

The DOHMH is working to provide clinical tools, diabetes resources and patient education materials to New Yorkers with diabetes and their health care providers. Better data will help us provide more timely and more focused resources, and will strengthen our partnership with patients and their health care providers.

Sincerely,

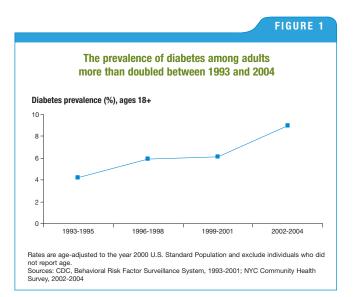
Thomas R. Frieden, MD, MPH

Commissioner

New York City Department of Health and Mental Hygiene

EXECUTIVE SUMMARY

espite advances in knowledge of diabetes care and control, diabetes was the 4th leading cause of death in New York City (NYC) in 2003, directly causing more than 1,800 deaths and contributing to thousands more. In the past decade, the prevalence of diagnosed diabetes has more than doubled among adults in NYC (Figure 1). More than 200,000 additional adult New Yorkers have diabetes but have not yet been diagnosed. This means that approximately 1 in 8 adults has diabetes. More than half of adult New Yorkers are overweight or obese, which increases the risk of diabetes.



- Uncontrolled diabetes is the leading cause of blindness, end-stage renal disease and non-traumatic lower extremity amputations in adults.
- Each year in NYC there are more than 20,000 hospitalizations with a principal diagnosis of diabetes.
- Although the hospitalization rate for diabetes has been stable in recent years, the increase in prevalence reflects a growing number of newly diagnosed, not yet hospitalized people.
- It is likely that diabetes-related hospitalizations will increase in the coming years.
- The health care costs attributed to diabetes and its complications are large and growing. The annual cost of hospitalizations with a principal diagnosis of diabetes - which reflects only a small portion of diabetes-related costs - doubled from 1990 to 2003, reaching \$481 million.

Diabetes disproportionately affects black and Latino New Yorkers, as well as those living in low-income households and neighborhoods. These disparities are evident in diabetes prevalence, hospitalizations and mortality, and track closely with patterns of overweight and obesity, and with the related behaviors of physical inactivity and

FIGURE 2

Diabetes and obesity have their greatest impact in New York City's poorest neighborhoods

	Low-income neighborhoods*	High-income neighborhoods*	Low-income neighborhoods higher by
Overweight and obesity prevalence (%)	61	47	1.3 times
Diabetes prevalence (%)	12	6	2 times
Diabetes hospitalization (per 100,000 population)	559	200	2.8 times
Diabetes mortality (per 100,000 population)	37	16	2.3 times

Percents and rates are age-adjusted to the year 2000 U.S. Standard Population. Percents exclude individuals who did not report age. Sources: NYC Community Health Survey, 2003; Bureau of Vital Statistics, NYC DOHMH, 2003; U.S. Census 2000/NYC Department of City Planning

unhealthy diet. However, neighborhood disparities in diabetes mortality and hospitalization are partly, but not completely, accounted for by differences in diabetes and overweight/obesity prevalence (Figure 2). Neighborhood disparities in diabetes morbidity and mortality may be influenced by differences in diabetes severity, access to health care or availability of healthy foods and places to exercise.

Regular medical monitoring and patient involvement in diabetes self-management can dramatically reduce rates of diabetes-related morbidity and mortality. Unfortunately, there is still a large gap between recommended health services and current practices. For example, among NYC adults with diabetes:

- More than one-third did not receive an eye or foot exam in the past year
- 57% did not get a flu vaccine in the past year
- 72% have never been immunized against pneumonia
- 77% do not take aspirin regularly
- 56% have never taken a diabetes self-management class

Some good news is that the majority of adults with diabetes report that during the past year they had a routine checkup, had their blood pressure and cholesterol levels checked, and were counseled on weight, nutrition and exercise at their last doctor's visit. However, while 4 in 5 adults with diabetes in NYC report having had at least 1 hemoglobin A1C test in the past year, only 16% of these adults know their A1C level. Furthermore, data from the NYC HANES revealed that more than half of all adults with diagnosed diabetes have hemoglobin A1C levels of 7% or greater, indicating that their blood sugar levels are not well controlled. In addition, most did not have their blood pressure or cholesterol within recommended levels.

Poorly controlled diabetes during pregnancy, whether chronic (diagnosed before pregnancy) or gestational (diagnosed during pregnancy), is associated with a higher risk of poor birth outcomes. The prevalence of diabetes during pregnancy grew 47% between 1990 and 2003, when it was present in more than 4% of all pregnancies. Maternal obesity increases the risk of diabetes during pregnancy.

The data in this report illustrate the magnitude of the diabetes problem in NYC and its disproportionate impact on low-income New Yorkers and the neighborhoods where they live.

INTRODUCTION

New York City, in parallel with the nation overall, is experiencing an epidemic of diabetes driven, in turn, by another epidemic - obesity. Dramatic disparities are evident, with low-income populations, blacks and Hispanics disproportionately affected.

Diabetes is a chronic condition characterized by high levels of blood glucose. It is caused by resistance to insulin (a hormone that regulates levels of blood glucose), inadequate production of insulin, or both. There are 3 main types of diabetes: type 1, type 2 and gestational. Type 1 diabetes has a peak incidence in puberty, but can develop at any age. Type 2 diabetes usually occurs in adults aged 40 and older who have certain inherited and behavioral risk factors, such as a family history of diabetes, or who are overweight, obese or physically inactive. However, with the rise in overweight and obesity at young ages, type 2 diabetes is increasingly affecting adolescents. Gestational diabetes occurs during pregnancy, when the body is less sensitive to insulin.

This report presents an overview of diabetes among New Yorkers as reflected in data from surveys, hospital discharge records and birth and death records. The chapters are organized around the types of data presented - prevalence, risk factors, hospitalizations, mortality, health care indicators and diabetes during pregnancy. Within the chapters, data on time trends, demographic patterns and disparities are presented. Detailed neighborhood-specific tables and maps are provided in **Appendix B**.

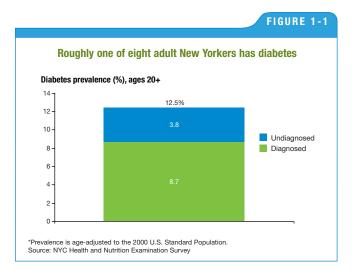
This report presents data on adults 18 and older, unless otherwise noted. Only statistically significant, robust findings are discussed. Rates are age-standardized to the U.S. Standard Population 2000, unless otherwise noted, to allow comparisons among populations within NYC, as well as to national data. For a complete description of the data used in compiling this report, see Appendix A.

Facts and figures alone cannot capture the challenge faced by the hundreds of thousands of New Yorkers living with diabetes. Nonetheless, these data serve to illuminate this complex problem and to guide a comprehensive public health response.

The Diabetes Prevention and Control Program strives to improve the quality of care and quality of life for New Yorkers with diabetes, and reduce the burden of diabetes, its complications, and of diabetes-related disparities in individuals, their families and communities. The program has a 5-point plan focused on prevention, improvement of diabetes quality of care, education, policy and advocacy, and surveillance and evaluation.

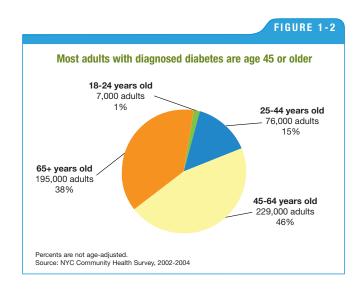


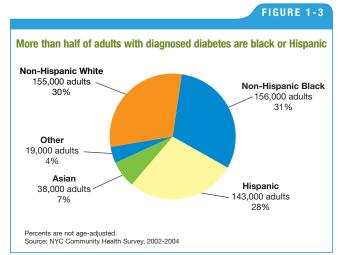
In 2004, about half a million adults had diagnosed diabetes, and another 200,000 had it but didn't know it-bringing the total number with diabetes to 700,000, or 12.5% of all New York City (NYC) adults (Figure 1-1). People with diabetes may have mild or no symptoms and often have it for 4 to 7 years before being diagnosed. There is no cure for diabetes, but once it is diagnosed, patients and health care providers can take action to control diabetes and reduce the risk of complications (see Chapter 5). The rest of this chapter describes the population of NYC adults who report they have been diagnosed with diabetes.

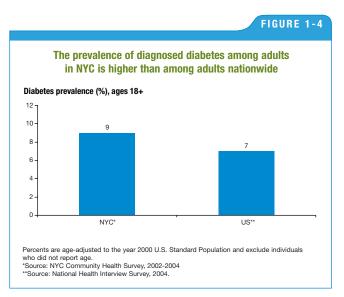


Among adults with diabetes, 84% are 45 or older (Figure 1-2), and 59% are black or Hispanic (Figure 1-3).

The citywide age-adjusted prevalence of self-reported diabetes among adults is 9%, which is 28% higher than the prevalence in the U.S. overall (Figure 1-4). Adults living in Highbridge-Morrisania, Hunts Point-Mott Haven, Williamsburg-Bushwick and East New York are most likely to report having diabetes (Figure 1-5). More neighborhood-level diabetes data are shown in tables and





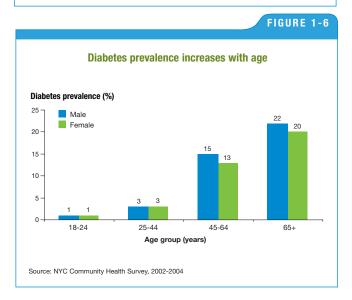


maps in **Appendix B**. The prevalence of self-reported diabetes among adults increases considerably with age among both men and women. More than 1 in 5 adults aged 65 and older reports having diabetes (Figure 1-6). Men are somewhat more likely than women to report having diabetes (10% vs. 8%).

Adults with the lowest household income are more than twice as likely to report having diabetes as adults with the highest household income (Figure 1-7). While the causes of disparities in diabetes prevalence are not fully

FIGURE 1-5 Diabetes prevalence varies by neighborhood Diabetes prevalence (%), ages 18+ 1.7 - 3.1 **Hunts Point-**3.2 - 6.9 7.0 - 9.6 9.7 - 12.9 **Mott Haven** Highbridge-Morrisania Williamsburg-Bushwick

East New York

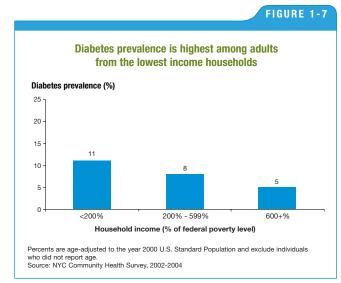


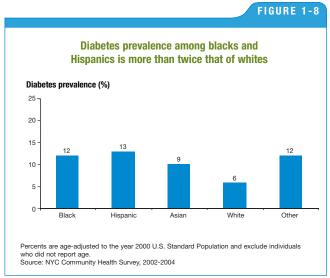
Prevalences are not age-adjusted.

Source: NYC Community Health Survey, 2002-2004

understood, economic disadvantage can make it more difficult to access healthy foods and exercise regularly, contributing to disparities in the prevalence of obesity, a major risk factor for diabetes (see Chapter 2).

Racial/ethnic disparities in diabetes prevalence exist, with the highest prevalence occurring among black and Hispanic adults (12% and 13%, respectively). In comparison, diabetes prevalence among whites and Asians is 6% and 9%, respectively (Figure 1-8).

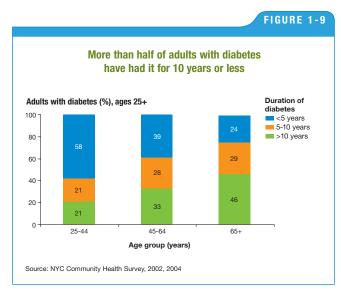


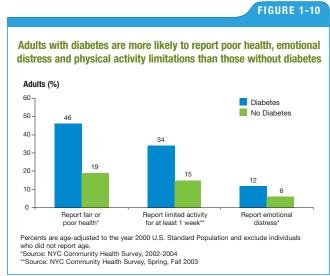


A number of studies have suggested that the risk of diabetes varies among Asian populations, with those of South Asian ancestry at highest risk. This pattern appears to hold true for NYC adults born in South Asia, among whom the prevalence of diabetes is more than 3 times higher than among those born in East Asia.1

Among adults aged 25 to 44, more than half have had diabetes for less than 5 years. Not surprisingly, older adults with diabetes are more likely to have had it longer, but more than half of adults 65 and older have had diabetes for 10 years or less (Figure 1-9). The large proportion of recently diagnosed adults will contribute to a growing burden of diabetes complications, which increase in frequency over time.

Nearly half (46%) of adults with diabetes say that their health is fair or poor, compared to 19% of adults without diabetes. In addition, adults with diabetes are twice as likely to report that their usual activity was limited by poor health for at least 1 week in the past month. Adults with diabetes were also twice as likely to report emotional distress, compared to adults without diabetes (Figure 1-10).



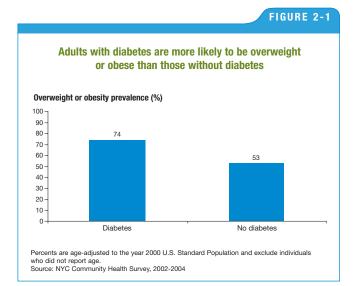


Age-adjusted diabetes prevalence among those age < 65 years was 11% for South Asians compared with 3% for East Asians. There were too few South Asians surveyed who were 65 and older for inclusion in this comparison.

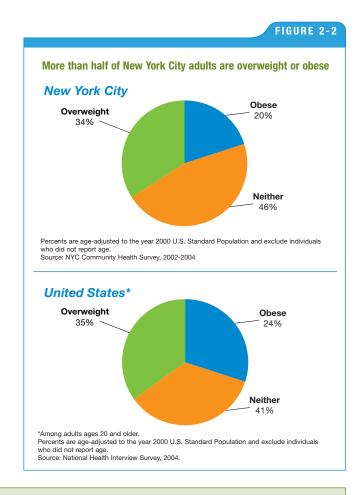


OBESITY AND RELATED RISK FACTORS

Patterns of overweight/obesity – and the related behaviors of physical inactivity and unhealthy diet - underlie the increasing prevalence and disparities in diabetes rates. Adults with diabetes are 40% more likely to be overweight or obese¹ than those without diabetes (Figure 2-1).



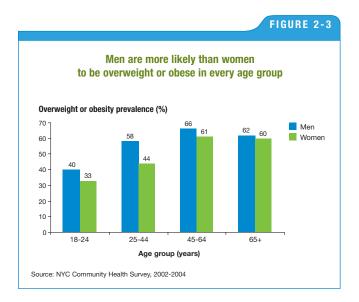
While the prevalence of overweight or obesity is lower in New York City than nationwide (54% vs. 65%), more than half of NYC adults are overweight or obese, and 1 in every 5 adults is obese (Figure 2-2).



Physical inactivity and unhealthy eating may lead to overweight or obesity – increasing a person's risk of developing diabetes.

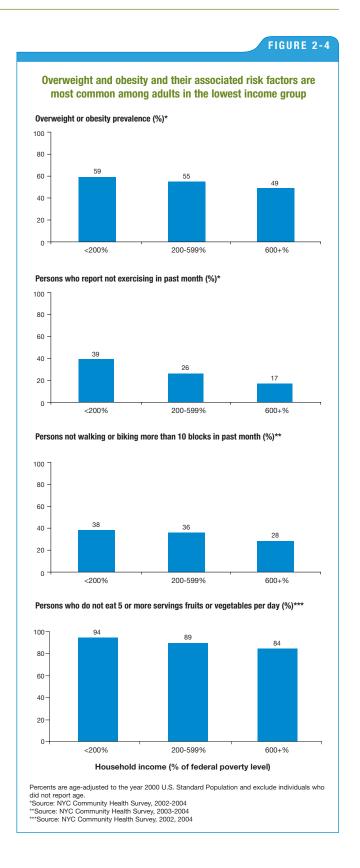
- 80% of adult New Yorkers do not get the recommended amount of exercise at least 30 minutes per day, 5 or more days per week.
- 30% of New York City adults report no leisure-time exercise in the past month.
- 36% report that they did not walk or bicycle at least 10 blocks while commuting or doing errands in the past month.
- 90% of adults eat fewer than the recommended 5 or more servings of fruits or vegetables per day.

Overweight and obesity are defined by an individual's body mass index (BMI), which is based on weight and height. An adult with a BMI between 25 and 30 is classified as overweight, and an adult with a BMI of 30 or greater is classified as obese.

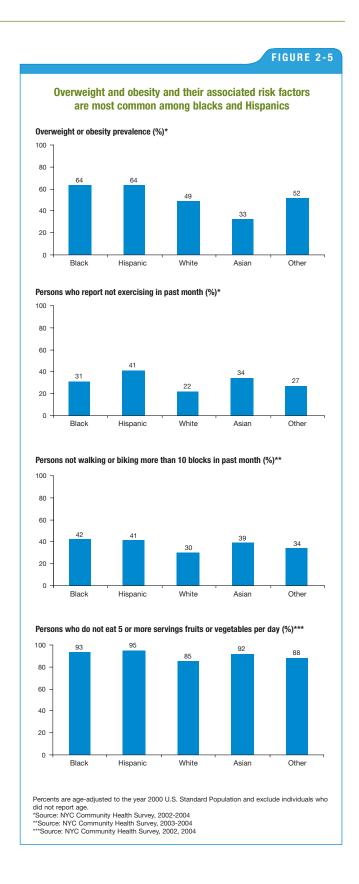


Like diabetes, the prevalence of overweight or obesity rises with age through age 64 and is greater in men than in women (Figure 2-3). The gender difference in overweight/obesity prevalence is driven by greater prevalence of overweight in men, since men are less likely than women to be obese.

Overweight or obesity is most common among adults with the lowest household income, and prevalence decreases with increasing income. Adults in the lowest income group are also more likely to report having risk factors associated with overweight or obesity - no leisure-time exercise, not walking or biking more than 10 blocks while commuting or doing errands and not eating the recommended servings of fruit and vegetables per day - compared to adults in the highest income group (Figure 2-4).



Overweight or obesity in NYC also differs by race/ethnicity. Nearly two-thirds of black and Hispanic adults are overweight or obese, compared to approximately half of whites and one-third of Asians. Compared to their white counterparts, blacks and Hispanics are also more likely to report having risk factors associated with overweight or obesity - no leisure-time exercise, not walking or biking more than 10 blocks while commuting or doing errands and not eating the recommended levels of fruit and vegetables per day (Figure 2-5).

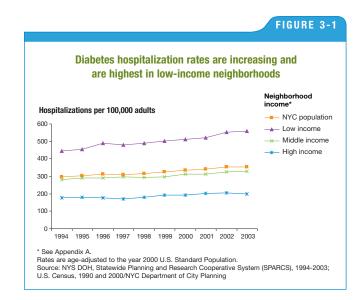


MORBIDITY: HOSPITALIZATIONS AND END-STAGE RENAL DISEASE

Diabetes is a common and costly cause of hospitalization in New York City. Many diabetes complications that lead to hospitalization can be prevented by effective diabetes management — including control of blood pressure, blood sugar and blood lipids through healthy eating, exercise and medication (see Chapter 5).

On the hospital discharge record, diabetes is sometimes listed as the principal diagnosis and other times as a listed diagnosis; in the latter instance, the principal diagnosis is often a condition in which diabetes is a contributing reason for admission (for example, cardiovascular disease). And sometimes, diabetes, while present, does not appear on the hospital discharge record. Therefore, while hospitalization data provide a useful overview of the problem, they do not fully capture the extent of diabetes-related hospitalization.

In 2003, there were 20,438 hospitalizations in NYC with a principal diagnosis of diabetes —355 per 100,000 adults. This rate is about the same as in 2002 — 354 per 100,000, compared to 200 per 100,000 nationwide. Between 1994 and 2003, the overall diabetes hospitalization rate in NYC increased by 20%, but rates were much higher in some neighborhoods. New Yorkers in low-income neighborhoods consistently experienced diabetes hospitalization rates nearly 3 times higher than those living in wealthier neighborhoods (Figure 3-1). While higher diabetes prevalence in low-income communities is one reason for this disparity, other



contributing factors include differences in disease severity and management.

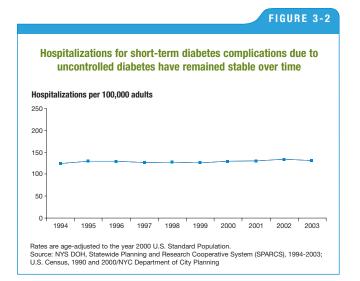
Most hospitalizations with diabetes as the principal diagnosis involve complications specific for diabetes. These hospitalizations are called "ambulatory care sensitive" because they can be prevented with effective outpatient care (see Appendix A).

Hospitalizations from short-term complications and uncontrolled diabetes

Short-term, potentially life-threatening complications of poorly controlled diabetes leading to hospitalization include diabetic ketoacidosis, hyperosmolarity and coma. Uncontrolled diabetes refers to blood glucose levels that put individuals with diabetes at risk for acute, potentially life-threatening complications.

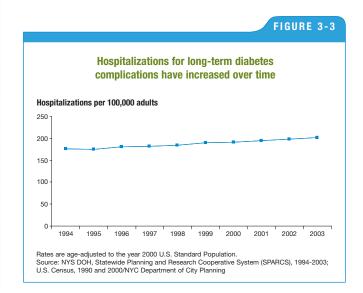
A goal of the U.S. Department of Health and Human Services (Healthy People 2010) is to decrease, by 2010, hospitalizations for short-term complications and uncontrolled diabetes to 54 hospitalizations per 100,000 adults 18 to 64. In 2003, the New York City hospitalization rate for short-term and uncontrolled diabetes was 116 per 100,000 adults 18 to 64 - which is more than twice as high as the Healthy People 2010 goal.

Of the 20,438 hospitalizations in 2003 with a principal diagnosis of diabetes, 38% were a result of short-term complications due to uncontrolled diabetes. NYC hospitalization rates for these conditions have remained fairly stable between 1994 and 2003, with 134 hospitalizations per 100,000 in 2003 (Figure 3-2).



Hospitalizations from long-term diabetes complications

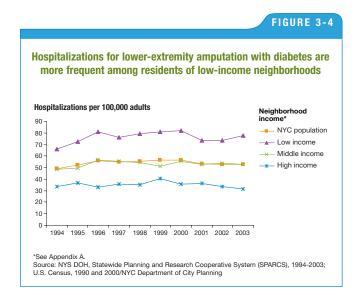
Long-term diabetes complications include kidney, eye, neurological and circulatory disorders. Diabetes can also lead to non-traumatic lower-extremity amoutations (LEA) by impairing circulation, sensation and resistance to infection. In 2003, of the 20,438 hospitalizations with a principal diagnosis of diabetes, 59% were a result of long-term complications. Between 1994 and 2003, hospitalizations for these conditions among persons with diabetes steadily climbed from 172 per 100,000 adults in 1994 to 212 per 100,000 adults in 2003, an increase of 23% (Figure 3-3). Since many adults in NYC have recently-diagnosed diabetes, hospitalizations for longterm complications will continue to rise as those New Yorkers live with the condition over time.



Non-traumatic lower-extremity amputations

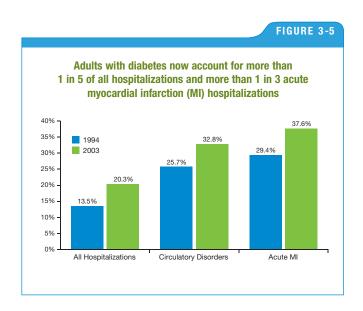
A common long-term complication of diabetes is LEA, but regular foot exams and care can prevent sores and infections that lead to amputation. In 2003, 75% of all LEAs occurred in adults with diabetes. Between 1994 and 2000, there was a general upward trend in diabetesrelated LEA hospitalization rates, which increased by 8% to 53 per 100,000 population during this period. However, rates then declined between 2000 and 2003. Since 1993, diabetes-related LEA hospitalization rates in low-income neighborhoods have been twice those in high-income neighborhoods (Figure 3-4).

Another way of expressing the LEA rate is per 1,000 persons with diabetes. In 2003, the LEA hospitalization rate was 4 per 1,000 persons with diabetes, a rate twice as high as the Healthy People 2010 goal of 1.8 per 1,000 persons with diabetes.



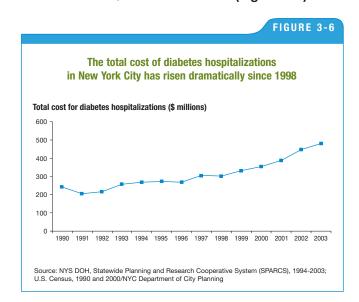
Hospitalizations with any mention of diabetes

In 2003 there were 191,366 hospitalizations among NYC adults for which diabetes was mentioned in any diagnosis field. This represented 20.3% of all hospitalizations among adults and since 1994, a 60% increase in the number of hospitalizations with a mention of diabetes. Diabetes increases the risk of heart disease and stroke, and is a listed diagnosis in nearly one-third of all hospitalizations for circulatory disorders. The number of acute myocardial infarction (MI) hospitalizations with mention of diabetes increased 39% from 1994 to 2003, when it represented 37.6% of all acute MI hospitalizations (Figure 3-5).

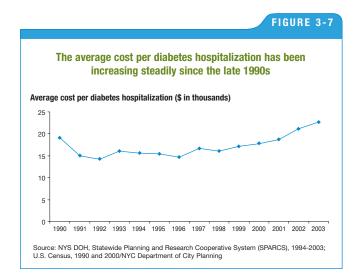


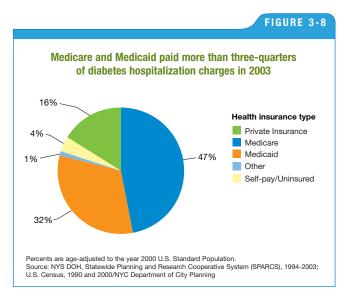
Cost of diabetes hospitalizations

Between 1990 and 2003, the total cost for hospitalizations with a principal diagnosis of diabetes doubled, from \$242 million in 1990 to \$481 million in 2003 (Figure 3-6).



This increase is due to both the rising number of hospitalizations in the past decade and the increase in average cost per hospitalization, which has risen steadily since the late 1990s (Figure 3-7). In 2003, Medicare and Medicaid paid for more than three-quarters of the cost of diabetes hospitalizations in NYC. Medicare was the major payor, assuming almost half of the total cost (Figure 3-8).





Treatment for end-stage renal disease

Renal (kidney) disease is a frequent long-term complication of diabetes and takes years to develop. Diabetes is the leading cause of end-stage renal disease (ESRD), and people with ESRD require either dialysis or a kidney transplant. Maintaining optimal control of blood sugar and blood pressure reduces the risk of developing ESRD. In 2004, of the 14,113 cases of ESRD receiving dialysis or a kidney transplant, 4,865 (34%) were due to diabetes (Figure 3-9).

			FIGURE 3-9			
End-stage renal disease, New York City, 2004						
	Total number	Number due to diabetes	Percent due to diabetes			
patients ¹	3,436	1,410	41%			

4.865

34%

¹ New cases are persons first diagnosed with ESRD during 2004.

New

Existing patients²

14,113

Among newly diagnosed cases of ESRD, 41% were due to diabetes, suggesting that this disease is increasingly caused by diabetes. In 2004, the total Medicare costs of ESRD due to diabetes reached almost \$8.2 billion nationally, up from \$4.7 billion in 1998. In New York State alone, Medicare costs of ESRD were \$527 million in 2004, (U.S. Renal Data System, 2006).

² Existing cases are persons living with ESRD as of 12/31/04. Source: U.S. Renal Data System, USRDS 2006 Annual Data Report: Atlas of End-Stage Renal Disease in the United States, National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2006

In 2003, diabetes was listed as the underlying cause of 1,819 New York City deaths. This reflects an ageadjusted mortality rate of 24 per 100,000 population, making diabetes the 4th leading cause of death among New Yorkers, up from 6th in 2002. More than half (952) of these diabetes deaths occurred before age 75. On average, each of these deaths resulted in 14 years of potential life lost before age 75 (YPLL75). Among New Yorkers, blacks had the highest rate of mortality (42 per 100,000 population) and YPLL75

(288 years per 100,000) from diabetes—2.8 and 2.3 times higher, respectively, than the rates among whites (Figure 4-1).

The number of deaths that list diabetes as the underlying cause greatly underestimates the overall impact of this disease on mortality. Diabetes also increases the risk of death from other conditions, including cardiovascular disease (the most common cause of death among people with diabetes), kidney disease and pneumonia.

FIGURE 4-1

The death rate from diabetes among blacks is nearly three times that of whites

	Number of deaths ¹	Deaths before age 75	Age-adjusted death rate/100,000 population	Average YPLL per death before age 75	YPLL/100,000 population <75 years of age
All New Yorkers	1,819	952	24	14	174
Black	653	366	42	15	288
Hispanic	400	250	32	14	160
White	583	235	15	14	127
Asian	90	57	17	11	84

¹ The sum of deaths by race/ethnicity will not equal the total number of deaths because residents with unknown or other race/ethnicity are not shown Rates are age-adjusted to the year 2000 U.S. Standard Population.
Source: Bureau of Vital Statistics, NYC DOHMH, 2003; U.S. Census 2000/NYC Department of City Planning

FIGURE 4-2

Diabetes is a contributing cause of thousands of deaths each year, most from cardiovascular disease

Underlying cause on death certificate	Total number of deaths ¹	Number of deaths with diabetes as contributing cause ²	Percent (%) of death certificates with any mention of diabetes as contributing cause
Cardiovascular disease	23,320	1,631	7%
Cancer	12,167	309	3%
Influenza and pneumonia	2,279	125	5%
Cerebrovascular disease	1,741	145	8%
Chronic lower respiratory disease	1,616	94	6%
Human immunodeficiency virus (HIV)	1,602	33	2%
Accidents except drug poisoning	950	28	3%
Nephritis, nephritic syndrome and nephrosis (includes renal failure)	677	50	7%
Septicemia	535	69	13%
Essential hypertension and renal diseases	305	55	18%
All deaths	55,448	2,943	5%

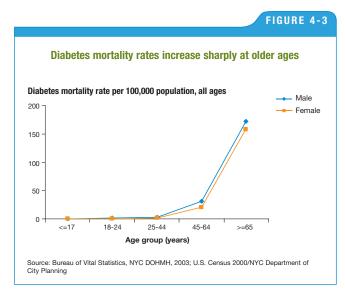
Total deaths by underlying cause as coded by NCHS differ from totals as coded by NYC Bureau of Vital Statistics and reported in 2002 Annual Summary.

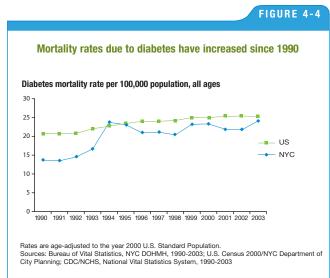
² The number of deaths from NCHS Multiple-Cause File excludes decedents with unknown residence in the NYC Vital Statistics mortality file. Source: NCHS Multiple-Cause Mortality File, 2002/analyzed by Bureau of Vital Statistics, NYC DOHMH

In such cases, diabetes may be listed as a contributing cause. In 2002, the most recent multiple-cause data available for NYC, diabetes was the underlying cause for 1,625 deaths and listed as a contributing cause on an additional 2,943 death certificates (NCHS, 2002) (Figure 4-2). Thus measured, diabetes caused or contributed to 8% of NYC deaths in 2002. This is likely to be an underestimate, as diabetes is underreported as an underlying or contributing cause of death nationwide. Among persons who die with diabetes, it is estimated that only 10% to 15% of death certificates list it as an underlying cause, and on 35% to 40% is it listed anywhere on the death certificate. (CDC, National Diabetes Fact Sheet, 2003).

Diabetes mortality rates increase sharply with age in both men and women. In 2003, the mortality rates among men and women aged 65 years and older were 5 and 8 times higher, respectively, than among those aged 45 to 64 years (Figure 4-3).

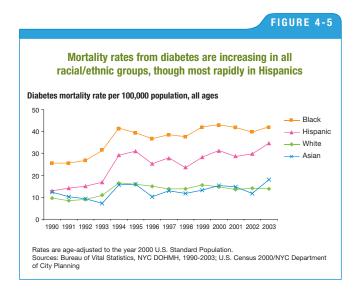
In NYC, diabetes mortality rates increased by 71% between 1990 and 2003, from 14 to 24 per 100,000 population. Historically, mortality rates have been lower in New York City than nationwide. However, since 1994 mortality rates in the city have been approaching national rates, and in 2003 the city and US rates were virtually identical (Figure 4-4).

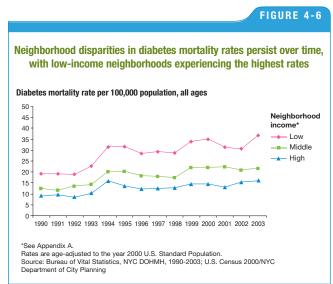




Diabetes mortality rates have increased over time among all racial/ethnic groups, but blacks and Hispanics have been disproportionately affected. For example, compared with white adults, the diabetes mortality rate among Hispanic adults was 1.4 times greater in 1990 but 2.5 times greater in 2003. While black New Yorkers have consistently had the highest diabetes mortality rates, Hispanics have experienced the greatest increase in mortality (169%) since 1990 (Figure 4-5).

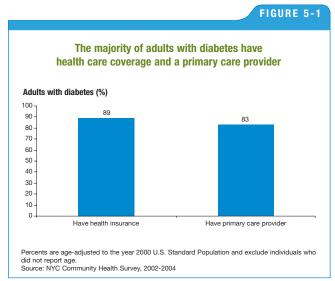
Between 1990 and 2003, diabetes mortality rates have increased in all NYC neighborhoods. However, mortality rates in low-income neighborhoods have been consistently 2 times higher than rates in high-income neighborhoods (Figure 4-6).

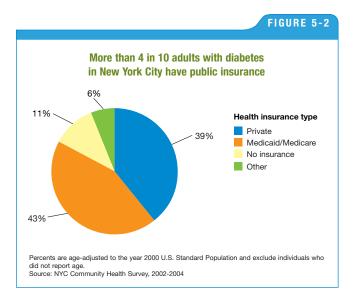




HEALTH CARE INDICATORS

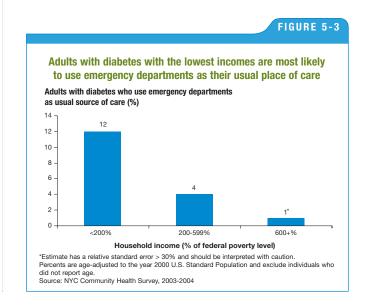
The risk of diabetes-related complications and mortality can be reduced with effective medical care. This chapter summarizes available data on access to health care for New Yorkers with diabetes and receipt of care that can reduce diabetes complications.



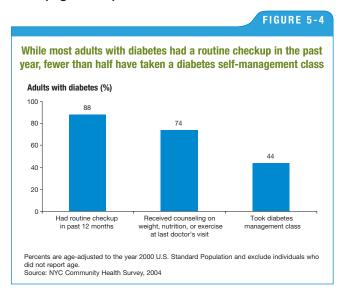


Having health insurance, a regular primary care provider and a usual source of care are important components of health care access. Among adults 18 and older with diabetes, the vast majority have health insurance and a primary care provider (Figure 5-1). More than 4 in 10 reported being covered by Medicaid or Medicare (Figure 5-2). Still, an estimated 35,000 adults with diabetes do not have insurance, and 62,000 do not have a primary care provider.

Obtaining routine medical care from an emergency department can indicate poor access to primary care and can lead to poor continuity of care. Among New Yorkers with diabetes, those with the lowest household incomes are 12 times more likely to use an emergency department as their usual source of care than those with high incomes (Figure 5-3).



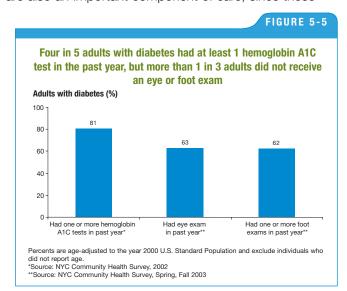
The majority of adults with diabetes had a checkup in the past year and received counseling on weight, nutrition or exercise at their last doctor's visit. However, only 44% have ever taken a diabetes self-management class (Figure 5-4).



While good diabetes management involves many lifestyle changes and health care measures, the most important actions are described as the **ABCs**: controlling blood sugar (defined as an <u>A</u>1C <7%), keeping <u>B</u>lood pressure below 130/80, keeping the level of LDL or 'bad' <u>C</u>holesterol below 100, and guitting or abstaining from **S**moking.

Improving control of blood glucose levels reduces the risk of diabetes complications affecting the heart, eyes, kidneys and nerves. A hemoglobin A1C test reflects the average amount of glucose in the blood over the past 2 to 3 months and is recommended at least twice a year

for persons with diabetes. Four in 5 adults with diabetes in New York City report having had at least 1 hemoglobin A1C test in the past year, but only 16% of those reporting a test know their A1C level. Eye and foot examinations are also an important component of care, since those

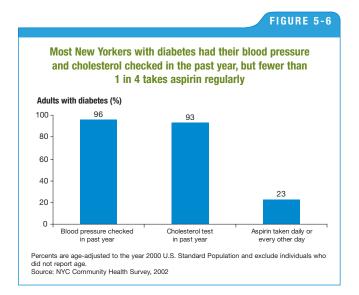


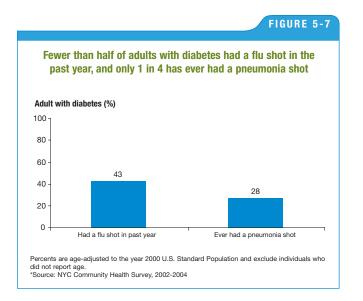
with diabetes are vulnerable to a variety of serious complications such as glaucoma, cataracts, retinopathy and lower-extremity amputations. While many New Yorkers with diabetes had an eye exam and at least 1 foot exam in the past year, more than 1 in 3 did not receive these exams (Figure 5-5).

For people with diabetes, control of high blood pressure and cholesterol levels to prevent cardiovascular disease is especially important. The great majority of adults with diabetes have had their blood pressure and cholesterol level checked in the past year, but available data suggest

Starting in January 2006, NYC DOHMH has mandated electronic laboratory reporting of hemoglobin A1C values to permit surveillance on the extent to which A1C levels are under adequate control – see www.nyc.gov/health/diabetes.

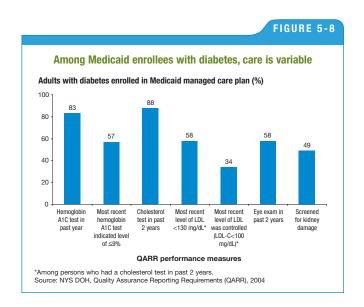
most do not have these risk factors well controlled (see page 5-4). Another strategy for preventing heart attacks among adults with diabetes is regular use of aspirin. Fewer than 1 in 4 New Yorkers with diabetes reports taking aspirin daily or every other day (Figure 5-6).





Although people with diabetes are at increased risk of complications or death from influenza and pneumonia, only 43% of adults with diabetes report having had a flu shot in the past year. Even fewer had ever received a pneumonia shot (28%) (Figure 5-7).

Data for a subset of low-income NYC adults with diabetes – those enrolled in Medicaid¹ – indicate that the vast majority received hemoglobin A1C tests in the past year. However, only 57% of those tested had a recent level of ≤9%, meaning that 43% had very poor control of blood glucose levels. Similarly, while 88% of those with diabetes had a cholesterol test in the past 2 years, only 34% had an LDL (low-density lipoprotein, or "bad" cholesterol) level less than 100 – the goal set in national guidelines for those with diabetes (NHLBI, 2001). Other diabetes care was not delivered consistently: 58% had an eye exam in the past 2 years and 49% were screened for kidney damage (**Figure 5-8**).

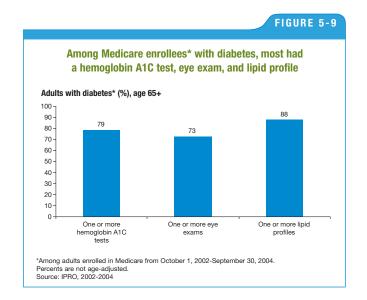


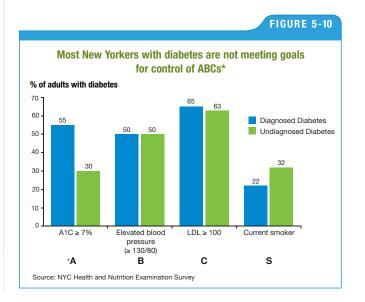
¹ New York State Department of Health's Quality Assurance Reporting Requirements (QARR) consist of a set of clinical and administrative performance indicators reported by managed care plans. For New York City adults with diabetes enrolled in Medicaid, QARR provides a way to assess the quality of care and the extent to which diabetes is well managed.

Among people with diabetes who were enrolled in Medicare² from April 2001 to March 2003, 79% had their hemoglobin A1C checked at least once, 73% had one or more eye exams, and 88% had their cholesterol level checked at least once, based on claims submitted (Figure 5-9).

Until recently, no systematic data on diabetes control were available for all NYC adults with the condition. Data from the 2004 NYC HANES show that most adults with diagnosed diabetes are not meeting goals for A1C, blood pressure or cholesterol (ABCs), and that 1 in 4 is a current smoker (Figure 5-10). For those with undiagnosed diabetes, the proportion not meeting goals for A1C, blood pressure or cholesterol is somewhat lower - probably because their diabetes developed more recently and is less severe.

Cigarette smoking increases the risk of developing both diabetes and diabetes-related complications, including cardiovascular disease, lower-extremity amputations, nerve damage and kidney disease. An estimated 1 in 3 adults with undiagnosed diabetes is a current smoker. Based on data from the Community Health Survey, among adults with diabetes who smoke, only 38% tried to quit using an effective cessation aid like nicotine patches, prescription medication or counseling. Health care providers can play a key role in reducing the impact of smoking by assessing smoking status at every visit, advising patients to quit and recommending or prescribing the use of medications and other effective cessation aids.





² The Medicare-eligible population includes those eligible because they are 65 or older or are disabled.

CHAPTER

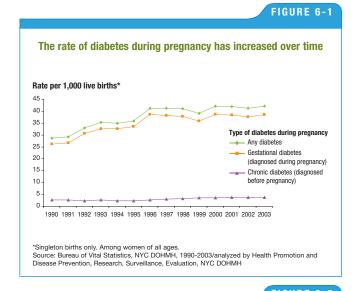
DIABETES DURING PREGNANCY

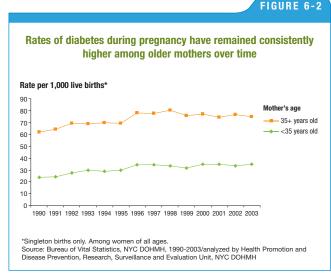
Metabolic changes during pregnancy can cause diabetes in women who did not have it before pregnancy; this is called "gestational diabetes." Gestational diabetes and diabetes present before pregnancy are associated with macrosomia (large-for-gestational-age babies), complications of labor and delivery, cesarean delivery, stillbirth, pre-term birth, congenital malformations and infant mortality. Preconception counseling for those with chronic diabetes and timely screening for pregnant women are essential to identify and treat diabetes during pregnancy. Birth records use a check box system to capture maternal diabetes. This chapter summarizes demographic patterns of diabetes during pregnancy, including chronic and gestational, as noted on birth records.

The rate of any diabetes during pregnancy among delivering mothers increased 47% between 1990 and 2003. Among mothers identified with diabetes on birth certificates, gestational diabetes is far more common than chronic diabetes. In 2003, rates of gestational and chronic diabetes were 39 and 4 per 1,000 live births, respectively (Figure 6-1).

The risk of any diabetes during pregnancy increases with maternal age. Between 1990 and 2003, the prevalence of diabetes during pregnancy was markedly higher among women 35 and older than among younger women. However, while the rate of diabetes during pregnancy

has increased in both age groups since 1990, women 34 and younger experienced a 46% increase, compared with a 20% increase among older women (Figure 6-2).

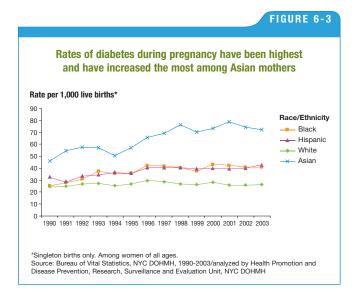




Because gestational diabetes is a risk factor for developing chronic diabetes, or may be the first indication of chronic diabetes, follow-up clinical evaluation for diabetes after pregnancy is essential for all those diagnosed with gestational diabetes.

A first-time diagnosis of diabetes during pregnancy can indicate onset of diabetes resulting from the pregnancy, or detection of pre-existing diabetes. Thus, when diabetes is first diagnosed during pregnancy, it may not be known whether it was present prior to the pregnancy. A new diagnosis of diabetes during pregnancy is recorded on birth records as gestational diabetes despite this uncertainty. Diabetes is recorded as chronic if it was diagnosed prior to pregnancy.

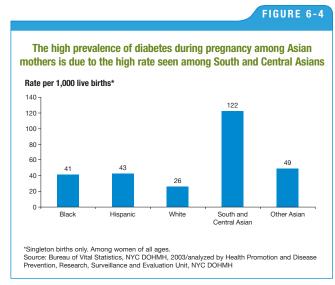
Between 1990 and 2003, the rate of any diabetes during pregnancy increased in all racial/ethnic groups, and disparities between groups widened. Rates of diabetes during pregnancy were highest and increased dramatically (by 57%) among Asian women - to 72 per 1,000 live births in 2003. Rates were lower among black women but rose most rapidly in this group (by 63%) (Figure 6-3).

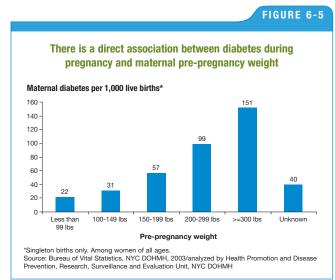


The high prevalence of diabetes during pregnancy among Asian mothers is most striking among South and Central Asians, with a rate of 122 per 1,000 live births. This represents 1 in 8 live births, a rate 2.5 times the rate in other Asian mothers, and more than 4.5 times the rate in white mothers (Figure 6-4).

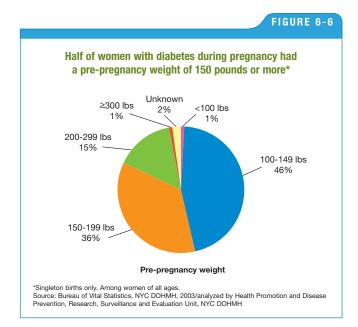
As with chronic diabetes, overweight and obesity increase the risk of diabetes during pregnancy. Although body mass index (BMI) during pregnancy cannot be determined from New York City birth certificates, pre-pregnancy weight recorded on birth certificates shows a strong,

direct relationship to diabetes. Compared to women reporting a pre-pregnancy weight of 100 to 149 pounds, the prevalence of diabetes during pregnancy is nearly twice as high among women reporting pre-pregnancy weights of 150 to 199 pounds and nearly five times greater (15% of pregnancies) for mothers weighing more than 300 pounds (Figure 6-5).





Half of women with diabetes during pregnancy reported a pre-pregnancy weight of 150 pounds or more, which would be overweight (BMI>25) for a woman of average height (5 feet, 4 inches) (Figure 6-6).





ABOUT THE DATA

Adult prevalence, health care indicators, risk factor data

The New York City Community Health Survey (CHS) is a telephone survey conducted among non-institutionalized adults aged 18 and older. The survey is based on the CDC Behavioral Risk Factor Surveillance System (BRFSS; CDC, 2005). The CHS used a stratified random sample of United Hospital Fund (UHF) neighborhoods in the city. Households were selected at random using a random digit dialing method. Interviews were conducted in many languages, including Spanish.

New York City Health and Nutrition Examination Survey (NYC HANES)

NYC HANES was a household-based examination survey conducted among non-institutionalized NYC adults aged 20 and older. The survey is based on the National Health and Nutrition Examination Survey (NHANES), NYC HANES used a 3-stage cluster sample to achieve a representative sample of NYC adults. Households and participants were randomly selected from 144 city neighborhoods. Those individuals comprising the sample participated in a health interview and brief examination. Interviews were conducted in English and Spanish; interpreters were used for other languages.

Hospitalization data

The Statewide Planning and Research Cooperative System (SPARCS; New York State Department of Health, 2006) data set consists of hospital discharge administrative records for acute care hospitals in New York State. Criteria for inclusion of SPARCS records in this fact book included (1) a diagnosis code for diabetes (AHRQ, 2005) and (2) residence in NYC as determined by zip code at the time of the hospitalization.

Interpretation and presentation of the SPARCS data present certain difficulties. The data represent numbers of hospitalizations, not numbers of individuals hospitalized. Since some persons with diabetes may be hospitalized repeatedly in any given year, the numbers or rates may overestimate the number of persons with diabetes hospitalized.

Additionally, SPARCS data on the race and ethnicity of individual patients are imprecise. These data are not collected in a standardized manner across hospitals. and large numbers of records have race listed as "other." Consequently, race/ethnicity-specific rates for diabetes hospitalization could not be calculated.

We used SPARCS data to estimate ambulatory caresensitive hospitalizations (AHRQ, 2001) which were identified and classified using the following ICD-9 codes:

Short-term diabetes complications and uncontrolled diabetes

250.10, 250.11, 250.12, 250.13, 250.20, 250.21, 250.22, 250.23, 250.30, 250.31, 250.32, 250.33

Long-term diabetes complications

250.40, 250.41, 250.42, 250.43, 250.50, 250.51, 250.52, 250.53, 250.60, 250.61, 250.62, 250.63, 250.70, 250.71, 250.72, 250.73, 250.80, 250.81, 250.82, 250.83, 250.90, 250.91, 250.92, 250.93

Hospital discharges that listed diabetes as a diagnosis were used to examine discharges involving lower extremity amputations (LEA) indicated by procedure code 84.10, 84.11, 84.12, 84.13, 84.14, 84.15, 84.16, 84.17, 84.18, 84.19. Discharges with a traumatic amputation diagnosis code (ICD-9 codes 895.0, 895.1, 896.0, 896.1, 896.2, 896.3, 897.0, 897.1, 897.2, 897.3, 897.4, 897.5, 897.6, 897.7) were excluded.

The LEA hospitalization rate per 1,000 persons with diabetes in 2003 was calculated using an estimate of the population with diabetes from the NYC Community Health Survey.

Treatment of end-stage renal disease (ESRD)

The United States Renal Data System (USRDS) is a data system that collects and distributes national data on end-stage renal disease (ESRD). The data reported here have been supplied by USRDS. The interpretation and reporting of these data are the responsibility of the author(s) and in no way should be seen as an official policy or interpretation of the U.S. government.

Mortality data

Mortality data are based on deaths of NYC residents whose underlying cause of death was diabetes. This categorization is selected in accordance with rules issued by the National Center for Health Statistics (NCHS) and codes of the International Classification of Diseases, Tenth Revision (ICD-10). Demographic data on death certificates are coded in agreement with NCHS standards. Interpretation of mortality data can be complicated because deaths with diabetes listed as underlying cause greatly underestimate the overall impact of diabetes on mortality. Studies have found that only 35% to 40% of persons who die with diabetes have it listed anywhere on the death certificate (CDC, National Diabetes Fact Sheet, 2003).

Census data

Population counts used as denominators for rates and to compute weights for the Community Health Survey are based on the year 2000 Census. Because of population growth since 2000, hospitalization and mortality rates may be overestimated, especially in neighborhoods where the population has increased significantly in recent years. Population estimates used to compute weights for the

NYC HANES were obtained from the 2004 American Community Survey and Current Population Survey, conducted by the Census Bureau.

Medicaid data

New York State Department of Health's Quality Assurance Reporting Requirements (QARR) provided data on health care indicators among Medicaid enrollees. QARR consist of a set of clinical and administrative performance indicators reported by managed care plans. For NYC adults with diabetes who are enrolled in Medicaid, QARR provides a way to assess the quality of care and the extent to which diabetes is well managed.

Medicare data

Data on health care indicators among Medicare enrollees were compiled from summary claims data analyzed and provided to NYC DOHMH by IPRO, Lake Success, New York.

Comparison data

National diabetes and obesity prevalence data were based on the National Health Interview Survey 2004 (Lethbridge-Cejku et al, 2006).

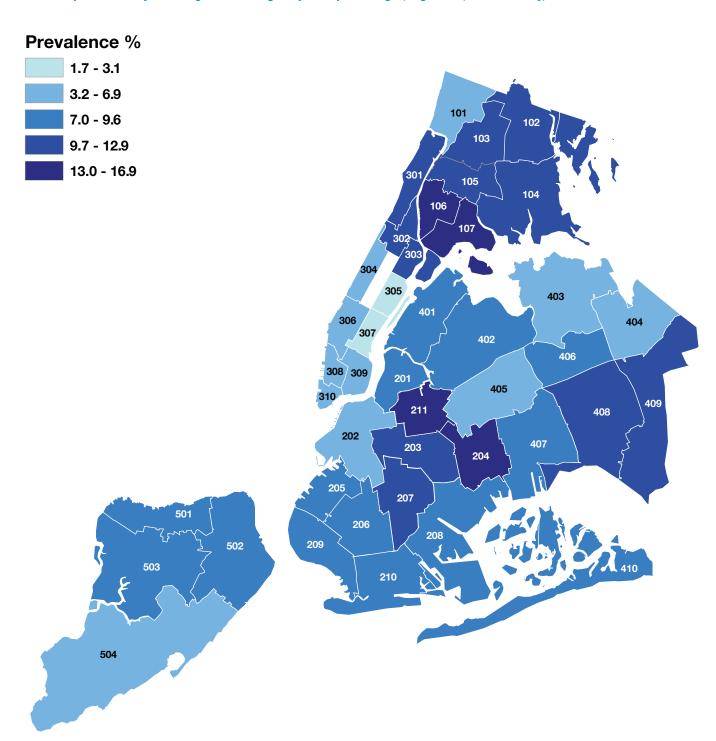
Presentation of data

Rates with relative standard errors (RSEs) of >30% indicated low reliability. These rates are either not presented or footnoted in the charts and/or tables. These rates should be interpreted with caution.

In this report, neighborhoods are groups of zip codes defined by the United Hospital Fund (UHF). Neighborhood income is defined by the percent of households in the neighborhood below 200% of the federal poverty guidelines and separated into thirds: low-income (45%-90%), middle-income (30%-44%) and high-income (<30%).

NEIGHBORHOOD TABLES AND MAPS

Diabetes prevalence by UHF neighborhood: age-adjusted percentage*, ages 18+, New York City, 2002-2004



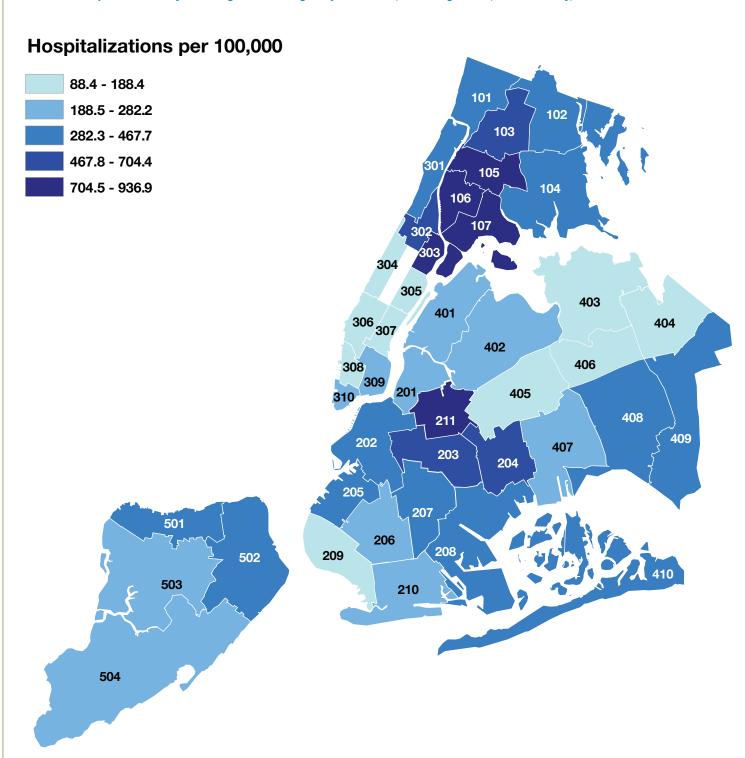
^{*} Percents are age adjusted to the year 2000 U.S. Standard Population.

Diabetes prevalence by borough and UHF neighborhood: number and age-adjusted percentage*, ages 18+, New York City, 2002-2004

UHF#	Neighborhood	Estimated number	Age-adjusted percent (%)*
	Bronx	102,000	12.1
101	Kingsbridge-Riverdale	5,000	6.1
102	Northeast Bronx	17,000	11.9
103	Fordham-Bronx Park	18,000	12.4
104	Pelham	23,000	11.1
105	Crotona-Tremont	12,000	11.4
106	Highbridge-Morrisania	16,000	16.5
107	Hunts Point-Mott Haven	11,000	16.9
	Brooklyn	164,000	9.7
	Greenpoint	6,000	7.7
	Downtown-Heights-Slope	8,000	5.8
	Bedford Stuyvesant-Crown Heights	24,000	12.3
	East New York	15,000	15.7
	Sunset Park	7,000	9.1
	Borough Park	19,000	8.3
	East Flatbush -Flatbush	22,000	10.5
	Canarsie-Flatlands	13,000	8.9
	Bensonhurst-Bay Ridge	12,000	7.3
	Coney Island-Sheepshead Bay	24,000	9.5
	Williamsburg-Bushwick	15,000	14.5
	Manhattan	76,000	6.6
		19,000	10.5
	Washington Heights-Inwood Central Harlem-Morningside Heights		12.0
	East Harlem	12,000	12.0
	Upper West Side	9,000 9,000	5.0
	Upper East Side		3.1**
	• •	6,000	
	Chelsea-Clinton	5,000	5.7 1.7**
	Gramercy Park-Murray Hill	2,000	
	Greenwich Village-SoHo	3,000	4.9
	Union Square-Lower East Side	9,000	6.4
	Lower Manhattan	1,000	5.5
	Queens	140,000	8.5
	Long Island City-Astoria	12,000	7.8
	West Queens	26,000	8.2
	Flushing-Clearview	13,000	5.9
	Bayside-Little Neck	5,000	6.1
	Ridgewood-Forest Hills	14,000	6.9
	Fresh Meadows	6,000	7.7
407	Southwest Queens	18,000	9.6
	Jamaica	22,000	11.1
	South East Queens	17,000	10.8
410	Rockaway	7,000	9.4
	Staten Island	23,000	7.1
	Port Richmond	4,000	9.0
	Stapleton-St. George	6,000	7.7
	Willowbrook	6,000	9.1
504	South Beach-Tottenville	7,000	5.1

Source: NYC Community Health Survey, 2002-2004
* Percents are age adjusted to the year 2000 U.S. Standard Population.
** Prevalence has a relative standard error > 30% and should be interpreted with caution.

Diabetes hospitalizations by UHF neighborhood: age-adjusted rate*, adults ages 18+, New York City, 2003



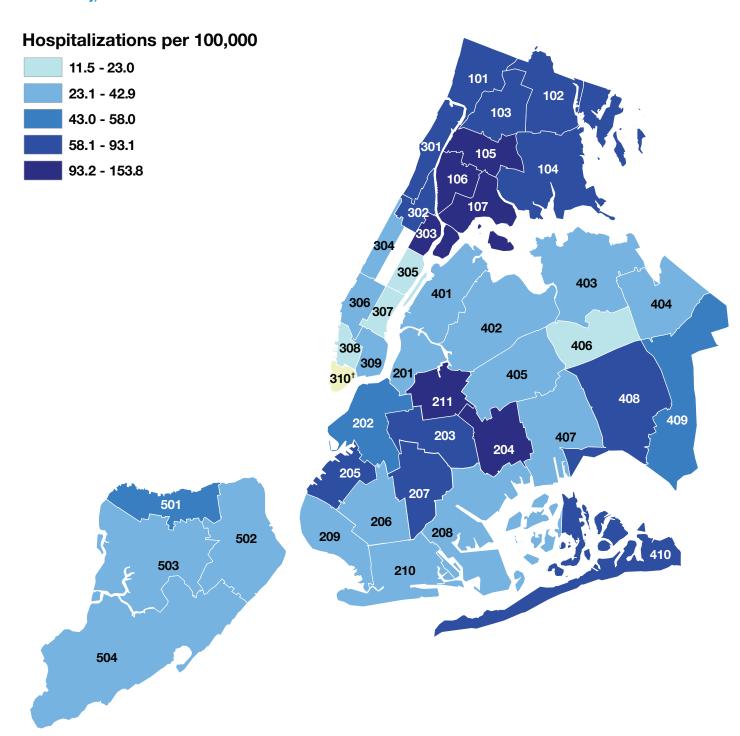
^{*} Rates are calculated using U.S. Census 2000 and age-standardized to the year 2000 U.S. Standard Population.

Diabetes hospitalizations by borough and UHF neighborhood: number of hospitalizations and age-adjusted rate*, adults ages 18+, New York City, 1994 and 2003

Bronx 3244 391 4870 566 45%	UHF#	Neighborhood	1994 Age-adjusted Number rate/100,000*		Number	2003 Age-adjusted Number rate/100,000* chan		
101 Kingsbridge		Brony						
102 Northeast Bronx	101							
103								
104 Pelham-Throgs Neck 625 309 849 406 32% 105 Crotona-Tremont 529 555 894 863 56% 106 Highbridge-Morrisania 592 632 930 914 45% 107 Hunts Point-Mott Haven 394 622 558 837 35%								
105								
106								
Brooklyn								
Brooklyn 249 330 214 282 -14%		0 0						
201 Greenpoint 249 330 214 282 -14% 202 Downtown-Heights-Slope 508 359 523 375 59% 203 Bedford Stuyvesant - Crown Heights 1105 560 1390 704 26%	107							
202		•						
Bedford Stuyvesant		•						
Crown Heights 1105 560 1390 704 26% 204 East New York 504 551 628 652 18% 205 Sunset Park 222 324 272 378 16% 206 Borough Park 481 211 519 216 3% 207 East Flatbush-Flatbush 696 347 937 468 35% 208 Canarsie-Flatlands 380 269 501 345 28% 209 Bensonhurst-Bay Ridge 329 197 306 178 -10% 210 Coney Island 602 240 644 253 6% 211 Williamsburg-Bushwick 764 705 1021 937 33% Manhattan 3093 263 3424 290 10% 301 Washington Heights-Inwood 595 338 748 420 24% 302 Central Harlem 557 723		• •	508	359	523	375	5%	
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502 Stapleton-St George 289 370 319 372 1% 503 Willowbrook 115 200 175 262 31%								
503 Willowbrook 115 200 175 262 31%								
504 South Beach-Tottenville 204 186 292 223 19%								
	504	South Beach-Tottenville	204	186	292	223	19%	

Source: NYS DOH, Statewide Planning and Research Cooperative System, 1994-2003 (updated April 2004); * Rates are calculated using U.S. Census 1990, 2000 and age-standardized to the year 2000 U.S. Standard

Lower-extremity amputation (LEA) with diabetes hospitalizations by UHF neighborhood: age-adjusted rate,* adults ages 18+, New York City, 2003



^{*} Rates are calculated using U.S. Census 2000 and age-standardized to the year 2000 U.S. Standard Population.

[†] Fewer than 6 cases. Rate not computed.

Lower-extremity amputation (LEA) with diabetes hospitalizations by borough and UHF neighborhood: number of hospitalizations and age-adjusted rate per 100,000* adults ages 18+, New York City, 1994 and 2003

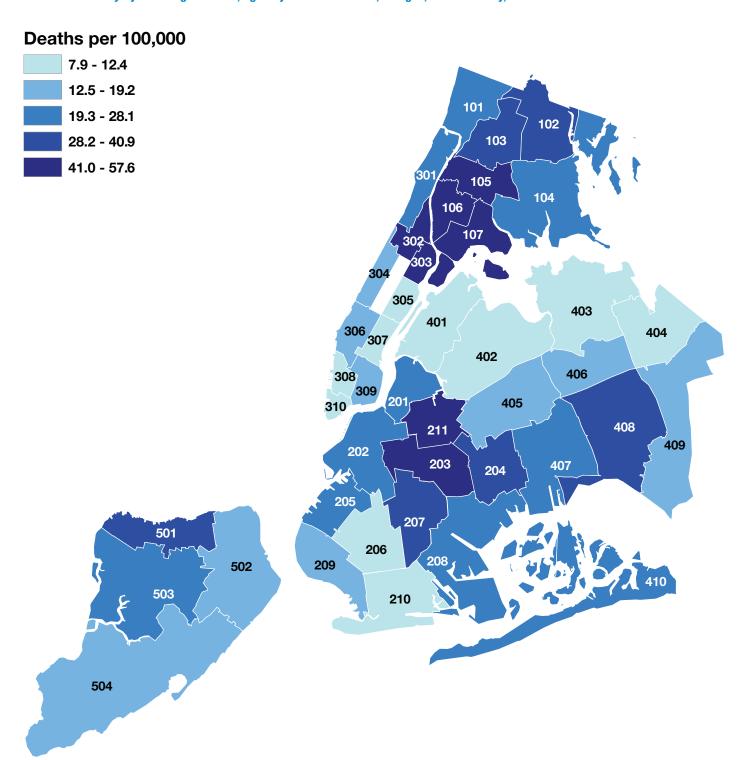
UHF#	Neighborhood	Number	1994 Age-adjusted rate/100,000	Number	2003 Age-adjusted rate/100,000	% change
	Bronx	590	73.7	721	87.9	19%
101	Kingsbridge	37	42.9	63	69.4	62%
102	Northeast Bronx	109	74.4	118	78.7	6%
103	Fordham-Bronx Park	95	69.7	126	93.1	34%
104	Pelham-Throgs Neck	146	72.5	154	74.3	2%
105	Crotona-Tremont	69	80.6	95	103.4	28%
106	Highbridge-Morrisania	83	99.9	102	112.4	13%
107	Hunts Point-Mott Haven	51	85.9	74	117.7	37%
	Brooklyn	828	50.8	907	53.6	6%
201	Greenpoint	27	37.9	29	38.4	1%
202	Downtown-Heights-Slope	74	58.1	75	57.4	-1%
203	Bedford Stuyvesant - Crown Heights	149	81.0	166	89.5	10%
204	East New York	64	81.5	85	98.3	21%
205	Sunset Park	18	27.5	46	68.2	148%
206	Borough Park	90	38.3	72	30.5	-20%
207	East Flatbush-Flatbush	88	49.2	130	69.1	40%
208	Canarsie-Flatlands	59	41.0	58	40.0	-2%
209	Bensonhurst-Bay Ridge	47	29.9	48	27.3	-9%
210	Coney Island	109	40.9	90	33.1	-19%
211	Williamsburg-Bushwick	103	104.6	108	106.4	2%
	Manhattan	500	43.9	510	44.7	2%
301	Washington Heights-Inwood	97	57.1	129	76.8	35%
302	Central Harlem	65	62.3	74	73.8	18%
303	East Harlem	78	115.9	108	153.8	33%
304	Upper West Side	78	44.7	64	36.7	-18%
305	Upper East Side	30	16.1	22	11.5	-29%
306	Chelsea-Clinton	45	45.8	30	31.0	-32%
307	Gramercy Park-Murray Hill	21	19.6	13	12.3	-37%
308	Greenwich Village-SoHo	11	19.7	12	18.9	-4%
309	Union Square-Lower East Side	66	44.1	55	36.8	-17%
310	Lower Manhattan	6	32.4	**	**	**
	Queens	620	38.8	695	42.0	8%
401	Long Island City-Astoria	44	29.2	48	32.9	13%
402	West Queens	86	30.3	122	40.1	32%
403	Flushing-Clearview	69	32.9	76	33.5	2%
404	Bayside-Little Neck	19	23.2	29	33.9	46%
405	Ridgewood-Forest Hills	85	42.2	60	29.4	-30%
406	Fresh Meadows	19	25.2	18	23.0	-9%
407	Southwest Queens	60	34.7	72	39.8	15%
408	Jamaica	116	61.4	134	67.2	9%
409	Southeast Queens	45	30.3	72	47.0	55%
410	Rockaway	69	83.5	63	79.6	-5%
	Staten Island	128	46.2	125	38.5	-17%
501	Port Richmond	22	60.7	23	58.0	-4%
502	Stapleton-St George	36	46.4	36	42.9	-8%
503	Willowbrook	30	53.5	25	36.4	-32%
504	South Beach-Tottenville	39	36.7	41	30.9	-16%

Source: NYS DOH, Statewide Planning and Research Cooperative System, 1994-2003 (updated April 2004)

Rates are calculated using U.S. Census 1990, 2000 and age-standardized to the year 2000 U.S. Standard Population.

^{**} Cells represent <6 persons and are not reported.

Diabetes mortality by UHF neighborhood, age-adjusted death rate*, all ages, New York City, 2002-2003



^{*} Rates are calculated using U.S. Census 2000 and age-standardized to the year 2000 U.S. Standard Population.

Diabetes mortality by borough and UHF neighborhood, number and age-adjusted death rate*, all ages, New York City, 1994-1995 and 2002-2003

UHF#	Neighborhood	Number of deaths [†]	1994-1995 Age-adjusted death rate/ 100,000*	Number of deaths [†]	2002-2003 Age-adjusted death rate/ 100,000*	% change
	Bronx	739	35	816	37.2	6%
101	Kingsbridge-Riverdale	52	19.1	72	25.2	32%
102	Northeast Bronx	130	30.6	156	37.1	21%
103	Fordham-Bronx Park	96	25.4	125	35.3	39%
104	Pelham-Throgs Neck	143	25.4	145	25.9	2%
105	Crotona-Tremont	81	42.3	109	56.8	34%
106	Highbridge-Morrisania	112	50.7	122	53.2	5%
107	Hunts Point-Mott Haven	79	57.6	89	57.6	0%
	Brooklyn	1,021	24.2	1.091	24.2	0%
201	Greenpoint	43	23.2	49	26.1	13%
202	Downtown-Heights-Slope	104	31.5	93	28.1	-11%
203	Bedford Stuyvesant- Crown Heights	171	37.0	209	43.9	19%
204	East New York	82	39.1	86	40.9	5%
205	Sunset Park	29	17.5	38	22.1	26%
206	Borough Park	108	15.7	86	12.1	-23%
207	East Flatbush-Flatbush	103	22.7	138	31.4	38%
208	Canarsie-Flatlands	61	16.6	93	24.7	49%
209	Bensonhurst-Bay Ridge	77	15.6	76	14.7	-6%
210	Coney Island-Sheepshead E	Bay 112	14.3	94	11.6	-19%
211	Williamsburg-Bushwick	102	42.1	129	54.0	28%
	Manhattan	690	23.3	590	19.4	-17%
301	Washington Heights-Inwood	d 103	23.3	109	24.7	6%
302	Central Harlem- Morningside Heights	131	45.9	123	45.0	-2%
303	East Harlem	1020	56.8	91	47.7	-16%
304	Upper West Side	68	14.1	68	14.1	0%
305	Upper East Side	53	10.2	42	8.5	-17%
306	Chelsea-Clinton	47	17.8	42	17.2	-3%
307	Gramercy Park-Murray Hill	27	9.6	22	7.9**	18%
308	Greenwich Village-Soho	27	18.7	15	9.9**	47%
309	Union Square-Lower East S		22.2	67	16.7	-25%
310	Lower Manhattan	16	33.0**	5	8.9**	73%
	Queens	707	16.8	780	17.4	4%
401	Long Island City-Astoria	71	17.5	49	12.3	-30%
402	West Queens	117	15.9	95	12.4	-22%
403	Flushing-Clearview	82	14.0	75	11.6	-17%
404	Bayside-Little Neck	21	10.0**	21	9.2**	8%
405	Ridgewood-Forest Hills	84	13.8	92	15.2	10%
406	Fresh Meadows	31	14.3	39	17.7	24%
407	Southwest Queens	91	20.2	116	24.7	22%
408	Jamaica	110	22.1	172	32.4	47%
409	Southeast Queens	42	11.2	66	17.4	55%
410	Rockaway	31	13.1	52	22.9	75%
	Staten Island	180	25.2	179	21.4	-15%
501	Port Richmond	33	35.8	31	30.3	-15%
502	Stapleton-St. George	46	21.6	44	19.2	-11%
503	Willowbrook	37	26.1	44	24.7	-5%
504	South Beach-Tottenville	59	21.6	60	18.4	-15%

Source: Bureau of Vital Statistics, NYC DOHMH, 1994-1995, 2002-2003

Rates are calculated using U.S. Census 1990, 2000 and age-standardized to the year 2000 U.S. Standard Population.

[†] Total number of deaths by neighborhood may not equal number of deaths by borough due to residents with

missing zip code.

** Mortality rate has a relative standard error > 30% and should be interpreted with caution.

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U.S. Food and Drug Administration



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FDA Home Page | CFSAN Home | Search/Subject Index | Q & A | Help

March 12, 2004

Calories Count Report of the Working Group on Obesity

Table of Contents

Memorandum of Transmittal

Executive Summary

OWG Principal Recommended Action Items

- 1. Introduction
 - 1. Public Health Impetus
 - 2. FDA Obesity Working Group
- 2. Foundations of this Report
 - 1. Scientific Principles
 - 2. FDA's Public Health Mission and Legal Authorities
 - 3. Stakeholder Participation
 - 4. The OWG's Work
- 3. Messages
 - 1. Obesity Knowledge Base
 - 2. Obesity Messages
 - 3. OWG Message Recommendations
- 4. Education Program to Deliver the Message
 - 1. Need for Education Programs
 - 2. OWG Education Recommendations
- 5. Supporting the Message
 - 1. Food Labels
 - 1. The Food Label
 - 2. FDA Focus Groups on Food Labels
 - 3. OWG Food Label Recommendations
 - 2. Restaurants/Industry
 - 1. FDA Focus Groups on Restaurants
 - 2. OWG Restaurant Recommendations
 - 3. OWG Diet Plan Recommendations
 - 3. Therapeutics

- 1. Background
- 2. FDA's Draft Guidance
- 3. Existing Therapies
- 4. OWG Therapeutics Recommendations
- 4. Research
 - 1. Joint Research with USDA/ARS
 - 2. Survey of Research
- 6. Stakeholder Investment to Help Ensure Results
 - 1. Background
 - 2. OWG Stakeholder Investment Recommendations
- 7. Overall Conclusions
- 8. References

List of Appendices

Appendix A - List of Acronyms and Abbreviations

Appendix B - TEXT BOXES on Body Mass Index (BMI), Energy (Calorie) Balance, and Carbohydrates and Other Macronutrient Contributions to Caloric Value

Appendix C - Notice Concerning July 30, 2003, Secretary's Roundtable on Obesity/Nutrition

Appendix D - August 11, 2003, Charge Memorandum

Appendix E - FDA Obesity Working Group Membership

Appendix F - FDA Obesity Working Group - Subgroup Members

Appendix G - Report from the Division of Market Studies Office of Scientific Analysis and Support, FDA

CFSAN - Helping Consumers Lead Healthier Lives through Better Nutrition: A Social Sciences Approach to

Consumer Information, Food Choices and Weight Management

Appendix H - Developing Effective Consumer Messages

Appendix I - Power of Choice

Memorandum of Transmittal

Date February 11, 2004

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 3 of 93

From Chair and Vice Chair, Obesity Working

Group

Subject Working Group Report and Recommendations

To Mark B. McClellan, M.D., Ph.D. Commissioner of Food and Drugs

We are pleased to transmit the final report and recommendations of the Food and Drug Administration's (FDA) Obesity Working Group (OWG). You established the OWG on August 11, 2003. The OWG met eight times from August 28, 2003, to January 22, 2004. In addition, the OWG held one public meeting, one workshop, two roundtable discussions (one with health professionals/academicians, and one with representatives of consumer groups), and solicited comments on obesity-related issues. The public meeting examined FDA's role and responsibilities in addressing the major health problem of obesity, focused on issues related to promoting better consumer dietary and lifestyle choices that have the potential to significantly improve the health and well-being of Americans, and obtained stakeholder views on how best to build a framework for messages to consumers about reducing obesity and achieving better nutrition. The science-based public workshop, which was cosponsored and funded by the Department of Health and Human Services Office of the Assistant Secretary for Planning and Evaluation, collected data relevant to FDA efforts to help consumer make better-informed weight management decisions. In addition, some members of the OWG met with representatives from various sectors of the packaged food and restaurant industries.

To accomplish its work, the OWG organized several subgroups (i.e., messages, education, food label, restaurants/industry, therapeutics, research, and stakeholder investment), each designed to focus on a particular aspect of the original charge to prepare a report that outlines an action plan to cover critical dimensions of the obesity problem from FDA's perspective and authorities. In addition, in order to inform its work, the OWG created a knowledge base subgroup. All the subgroups, in turn, met separately and developed respective analyses and recommendations, which serve as the basis for this report.

The report that follows provides, for your consideration, a range of short- and long-term recommendations that are responsive to the charge. The OWG believes that, if the report's recommendations are implemented, they will make a worthy contribution to confronting our Nation's obesity epidemic and helping consumers lead healthier lives through better nutrition. The report also contains a number of appendices, including your original charge memo, the list of OWG members and subgroups, and other supporting material.

We appreciate the opportunity to have served FDA as leaders of the OWG, and we stand ready to facilitate the implementation of the OWG's recommendations.

Lester M. Crawford, D.V.M., Ph.D. Chair Deputy Commissioner of Food and Drugs Robert E. Brackett, Ph.D. Vice Chair Director Center for Food Safety and Applied Nutrition

Executive Summary

Obesity is a pervasive public health problem in the United States. Since the late 1980s, adult obesity has steadily and substantially increased in the United States. Today, 64 percent of all Americans are overweight and over 30 percent are obese; in 1988 through 1992, fewer than 56 percent were overweight and fewer than 23 percent of American adults were obese. The trends for children are even more worrisome. Recent research by the U.S. Centers for Disease Control and Prevention⁽¹⁾ (CDC) shows that 15 percent of children and adolescents aged 6 to 19 are overweight -double the rate of two decades ago (CDC, 2003). As Americans get heavier, their health suffers. Overweight and obesity increase the risk for coronary heart disease, type 2 diabetes, and certain cancers. According to some estimates, at least 400,000 deaths each year may be attributed to obesity (Mokdad, *et al.*, 2004).

To help confront the problem of obesity in the United States and to help consumers lead healthier lives through better nutrition, on August 11, 2003, Mark B. McClellan, M.D., Ph.D., Commissioner of Food and Drugs, created the Food and Drug Administration's (FDA) Obesity Working Group (OWG). He charged the OWG to prepare a report that outlines an action plan to cover critical dimensions of the obesity problem from FDA's perspective and authorities.

This report reflects the work of the OWG to meet the Commissioner's charge and is organized largely around the specific elements of the August 11, 2003, charge.

The problem of obesity has no single cause. Rather, it is the result of numerous factors acting together over time. Similarly, there will be no single solution; obesity will be brought under control only as a result of numerous coordinated, complementary efforts from a variety of sectors of society. Nor can this problem be solved quickly. Any long-lasting reversal of this phenomenon will itself be a long-term process.

The OWG's recommendations are centered on the scientific fact that weight control is primarily a function of balance of the calories eaten and calories expended on physical and metabolic activity (see Appendix B Text Boxes in the report for a fuller discussion). The recommendations contained in this report therefore focus on a "calories count" emphasis for FDA actions. The box on the next page contains the OWG's principal recommendations. The body of this report details the underlying rationale for each of these principal recommendations and additional recommendations. Taken together, they represent a plan of action, founded on science, FDA's public health mission and legal authorities, and the importance of considering consumer and other stakeholder views and needs in addressing obesity.

OWG Principal Recommended Action Items

Food Labeling

• Calories: Issue an advance notice of proposed rulemaking (ANPRM) to solicit public comment on how

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 5 of 93 to give more prominence to calories on the food label. As examples, increasing the font size for calories, including a percent Daily Value (%DV) column for total calories, and eliminating the listing for calories from fat.

- Serving Sizes: Encourage manufacturers immediately to take advantage of the flexibility in current regulations on serving sizes and label as a single-serving those food packages where the entire content of the package can reasonably be consumed at a single-eating occasion. For example, a 20 oz bottle of soda that currently states 110 calories per serving and 2.5 servings per bottle could be labeled as containing 275 calories per bottle.
- Carbohydrates: File petitions and publish a proposed rule during summer 2004 to provide for nutrient content claims related to carbohydrate content of foods, including guidance for use of the term "net" in relation to the carbohydrate content of foods.
- Comparative Labeling Statements: Encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to make healthy substitutions, including calories (e.g., "instead of cherry pie, try our delicious low fat cherry yogurt 29 percent fewer calories and 86 percent less fat").

Enforcement Activities

- Together with the Federal Trade Commission (FTC), increase enforcement against weight loss products having false or misleading claims.
- Consider enforcement action against products that declare inaccurate serving sizes.

Educational Partnerships

• As part of a larger DHHS effort, establish relationships with, among others, youth-oriented organizations such as the Girl Scouts of the USA, the National Association of State Universities and Land Grant Colleges (4-H program), to educate Americans about obesity and leading healthier lives through better nutrition.

Restaurants

• Urge the restaurant industry to launch a nation-wide, voluntary, and point-of-sale nutrition information campaign for consumers.

Therapeutics

- Convene a meeting of a standing FDA advisory committee meeting to address challenges, as well as gaps in knowledge, about existing drug therapies for the treatment of obesity.
- Revise 1996 draft guidance on developing obesity drugs and re-issue for comment.

Research

- Support and collaborate, as appropriate, on obesity-related research with others, including NIH.
- Pursue research on obesity prevention with U.S.Department of Agriculture/Agricultural Research Service (USDA/ARS).

 $(\underline{}^{\underline{1}})$ See Appendix A for a list of acronyms and abbreviations used throughout this report.

Food Labeling and Nutrition | Calories Count

<u>CFSAN Home</u> | <u>CFSAN Search/Subject Index</u> | <u>CFSAN Disclaimers & Privacy Policy</u> | <u>CFSAN Accessibility/Help</u>
<u>FDA Home Page</u> | <u>Search FDA Site</u> | <u>FDA A-Z Index</u> | <u>Contact FDA</u>

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FDA Home Page | CFSAN Home | Search/Subject Index | Q & A | Help

March 12, 2004

Counting Calories Report of the Working Group on Obesity

Table of Contents

I. Introduction

A. Public Health Impetus

The nation is currently facing a major long-term public health crisis. In recent years, unprecedented numbers of Americans of all ages have become either overweight or obese. This trend toward overweight and obesity has accelerated during the past decade and is well documented (see Box 1) by numerous scientific analyses. (For convenience, future use in this document of the term obesity includes both overweight and obesity.) Unfortunately, this trend towards obesity shows no signs of abating. If it is not reversed, the gains in life expectancy and quality of life resulting from modern medicine's advances on disease will erode, and more health-related costs will burden the nation's healthcare systems. For these reasons, the trend toward obesity must be reversed.

Box 1 - Facts and Figures on Overweight and Obesity

The scope of the growing and urgent public health problem of obesity is outlined in the Surgeon General's Call to Action (DHHS, 2001). In 1999-2000, 64% of U.S. adults were overweight, increased from 56% when surveyed in 1988-1994; 30% of adults were obese, increased from 23% in the earlier survey (DHHS, 2003; Flegal *et al.*, 2002). Among children age 6 through 19 years, 15% were overweight, compared with 10 to 11% in the earlier survey (CDC, 2003; Ogden *et al.*, 2002). Overweight and obesity are associated with increased morbidity and mortality. It is estimated that about 400,000 deaths per year may be attributed to obesity, and overweight and obesity increase the risk for coronary heart disease, type 2 diabetes, and certain cancers (Mokdad, *et al.*, 2004). The total economic cost of obesity in the United States is up to \$117 billion per year (DHHS, 2003), including more than \$50 billion in avoidable medical costs, more than 5 percent of total annual health care expenditures (DHHS, 2001; DHHS, 2003).

The prevalence of overweight and obesity varies by gender, age, socioeconomic status, and race and ethnicity (DHHS, 2001). For example, although overweight has increased among all children, the prevalence of overweight and obesity is significantly higher among non-Hispanic black and Mexican-American adolescents than among non-Hispanic white teens (12-19 years old) (Ogden *et al.*, 2002). A majority of non-Hispanic black women over 40 are overweight or obese (Flegal *et al.*, 2002).

The problem of obesity in America has no single cause. Rather, obesity is the result of multiple factors acting together over time, including genetic (Loos and Bouchard, 2003) and environmental factors (Hill and Peters, 1998; Hill *et al.*, 2003). Similarly, there will be no single solution to the problem of obesity; it will be brought under control only as a result of coordinated, complementary efforts from a variety of sectors of society. The obesity epidemic also will not be solved quickly. Any long-lasting reversal of this phenomenon will itself be a long-term process.

Obesity is associated with significant health problems in the pediatric age group and is an important risk factor associated with adult morbidity and mortality. The causes and mitigation of childhood obesity have been and continue to be the focus of much attention (Hill and Trowbridge, 1998; Barlow and Dietz, 1998; Ashton, 2004; Bowman, *et al.*, 2004). A policy statement of the American Academy of Pediatrics proposes strategies for early identification of excessive weight gain by using BMI, ⁽⁴⁾ for dietary and physical activity interventions during health supervision encounters, and for advocacy and research (AAP, 2003). According to Ritchey and Olson (1983), parental behavior is a dominant influence on children's eating habits. For adults, the literature discusses how having a specific behavior goal for the prevention of weight gain (e.g., increasing physical activity or eating less at each meal) may be key to arresting the obesity epidemic (Wyatt and Hill, 2002; Hill, 2004). In similar fashion, the *Dietary Guidelines for Americans* includes a chapter on physical activity, linking physical activity with nutrition.

The combined efforts of Federal, state and local governments, the packaged food industry, the restaurant industry (including both quickservice and other types of restaurants), the professional health community (including primary care physicians, nutritionists, dietitians, and others), consumer advocacy groups, schools, the media and, of course, committed individuals will all be required to contribute to the solution to the problem of obesity.

The current crisis has been recognized by many of these groups, including a number of our stakeholders, for some time, and many wide-ranging efforts to address and reverse the trends that lead to obesity are already underway. Within the DHHS, Secretary Tommy G. Thompson has led efforts to address the public health problem of obesity. On July 30, 2003, Secretary Thompson convened a roundtable on obesity/nutrition involving experts from academia, the health professions, industry, and government to consider the role that the Department can play in reducing or reversing the weight gain that leads to obesity (see Appendix C for the five questions presented at the roundtable). DHHS also established a Docket in FDA (Docket No. 2003N-0338) to gather additional information on this topic.

Each group now working on the problem of obesity brings unique resources and expertise to bear on it. Among

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 9 of 93 the major Federal government entities with a responsibility and a capability to address the problem, FDA, within the broader context of DHHS, is bringing its own unique strengths to bear, including relevant legal authorities.

B. FDA Obesity Working Group

In a memorandum dated August 11, 2003 (see Appendix D for the August 11 memorandum), Commissioner of Food and Drugs Mark B. McClellan, M.D., Ph.D., created the OWG and gave it its charge. FDA Deputy Commissioner Lester M. Crawford, D.V.M., Ph.D., chairs the OWG; the Director of FDA's Center for Food Safety and Applied Nutrition (CFSAN), Robert E. Brackett, Ph.D., is the vice-chair. Other members of the OWG (see Appendix E for list of OWG members) were selected from across FDA to provide expertise and knowledge in a range of relevant scientific and other disciplines. The Commissioner requested that the OWG deliver, in six months, a report that outlines an action plan covering critical dimensions of the obesity problem as outlined in the charge and to help consumers lead healthier lives through better nutrition.

During its tenure, the OWG met eight times; received briefings from several invited experts from other government agencies; held one public meeting, one workshop, two roundtable discussions (one with health professionals/academicians, and one with representatives of consumer groups); and solicited comments on obesity-related issues, directing them to the Docket that DHHS established in July 2003 (Docket No. 2003N-0338). In addition, some members of the OWG met with representatives from various sectors of the packaged food and restaurant industries.

To accomplish its work, the OWG organized several subgroups (see Appendix F for list of OWG subgroups), each designed to focus on a particular aspect of the Commissioner's original charge. In addition, in order to inform its work, the OWG created a knowledge base subgroup. All the subgroups, in turn, met separately and developed respective analyses and recommendations, which serve as the basis for this report. This report presents the OWG's recommendations that are responsive to the Commissioner's charge, and that the OWG believes can contribute to confronting obesity in the United States.

II. Foundations of this Report

Any FDA effort to address obesity must be based on the following: (a) adherence to fundamental scientific principles; (b) conformance with FDA's public health mission and legal authorities; and (c) consideration of consumer and other stakeholder views and needs.

A. Scientific Principles

Fundamentally, obesity represents an imbalance between energy intake (e.g., calorie intake) and energy output (expended both as physical activity and metabolic activity; see text box on Calorie (Energy) Balance at Appendix B). Although there is much discussion about (1) the appropriate makeup of the diet in terms of relative proportions of macronutrients (fats [lipids], carbohydrates, and protein) that provide calories and (2) the foods that provide these macronutrients, for maintenance of a healthy body weight it is the consumption and expenditure of calories that is most important. In other words, "calories count." (6)

1. Calories

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 10 of 93

Quite simply, the OWG's recommendations center on the scientific fact that weight control requires caloric balance. Food supplies the energy that provides fuel for the body and for rebuilding the "wear and tear" one is subjected to during the day. The traditional unit for expressing the energy value of foods is the *kilocalorie* (kcal). The term *calorie* is commonly used in place of kilocalorie. One calorie is equal to 4.184 kilojoules (kjoules) a common unit of energy used in the physical sciences and internationally in nutrition labeling. The caloric intake that is appropriate for an individual depends on a number of factors, including height, weight, gender, and age.

2. Calorie Contribution of Macronutrients

Attention to caloric intake is a key element of weight control (the other is caloric expenditure). The three macronutrients that provide energy in our diets are carbohydrate, protein, and fat (see text box on Carbohydrates and Other Macronutrient Contributions to Caloric Value at Appendix B). (Alcohol is also a source of energy, yielding 7 calories per gram, but it is not a nutrient. (7) These macronutrients yield different amounts of energy in the form of calories per unit weight.

- Carbohydrate = 4 calories per gram
- Protein = 4 calories per gram
- Fat = 9 calories per gram

To maintain a constant bodyweight over time, "energy in" from food must equal "energy out" as a result of resting metabolism plus physical activity. In other words, calories eaten should equal the calories expended on a daily basis. Bodyweight will change if one alters this basic balance. If one consumes even slightly more calories than one expends over time, one will eventually gain weight (Wright, *et al.*, 2004). Conversely, if one consumes fewer calories than one expends over time, one will eventually lose weight.

B. FDA's Public Health Mission and Legal Authorities

FDA's mission is to promote and protect the public health. It seeks to accomplish this mission by enforcing the laws it is charged with administering and by conducting educational and public information programs relating to its responsibilities.

The Federal Food, Drug, and Cosmetic Act (the Act) as amended by the Nutrition Labeling and Education Act of 1990 (NLEA, Public Law 101-535), together with FDA's implementing regulations, established mandatory nutrition labeling for packaged foods to enable consumers to make more informed and healthier food product choices in the context of the total daily diet. The statute and the regulations were also intended to provide incentives to food manufacturers to improve the nutritional quality of their products.

The cornerstone of the NLEA is the Nutrition Facts panel (NFP), which lists the total number of calories derived from any source, as well as the total number of calories derived from total fat. The amounts of total fat, saturated fat, cholesterol, sodium, total carbohydrate, dietary fiber, sugars, and protein in the food are also listed in the NFP, both as the quantitative "amount per serving" (grams or milligrams) and, with the exception of sugars and protein, as the percent of a dietary reference value, called the "percent Daily Value" (%DV). FDA requires the declaration of nutrients as a %DV, in part to help consumers understand the role of individual foods in the context of the total daily diet. Also, to help consumers determine how their individual dietary needs compare with the reference daily values used on the label, the NFP includes a footnote that specifies that the

reference daily values are based on a 2,000 calorie diet. On larger packages, the footnote goes on to list the daily values for total fat, saturated fat, cholesterol, sodium, total carbohydrate, and dietary fiber for both a 2,000 and a 2,500 calorie diet.

As part of FDA's regulations implementing the NLEA, the agency established reference amounts customarily consumed (RACCs) for 139 food categories that manufacturers are to use in developing serving sizes that are then expressed in household measures (e.g., teaspoons, cups, pieces). These serving sizes become the basis for reporting the amount of each nutrient present and enable consumers to compare the nutritional qualities of similar food products.

Under the NLEA, FDA also has authority over health claims and nutrient content claims for foods. Appropriate health claims and nutrient content claims, like nutrition labeling, further the statutory objectives of enabling consumers to make more informed and healthier food product choices and encouraging manufacturers to improve the nutritional quality of their products.

A health claim is a claim that characterizes the relationship between a food, or a food component, and a disease or a health-related condition, and may only be made in accordance with an authorizing regulation issued by FDA. An example of a health claim is: "Although many factors affect heart disease; diets low in saturated fat and cholesterol may reduce the risk of heart disease." A nutrient content claim is a claim that characterizes the level of a nutrient in a food, and it, too, must be made in accordance with an authorizing regulation issued by the agency. Nutrient content claims describe the level of a nutrient or dietary substance in the product, using terms such as "free," "high," and "low," or they compare the level of a nutrient in a food to that of another food, using terms such as "more," "reduced," and "lite." More information on FDA's implementation of these authorities can be found at http://www.cfsan.fda.gov/~dms/hclaims.html.

Restaurants, unlike the manufacturers of packaged foods, are not required by the NLEA to provide nutrition information for a menu item or meal unless a nutrient content claim or a health claim is made for such item or meal. When such a claim is made, the restaurant need only provide information on the amount of the nutrient that is the basis of the claim. Thus, for example, if a restaurant claims that a particular menu item is "low in fat" (i.e., makes a nutrient content claim with regard to fat) then this requirement is satisfied by adding: "low fat - provides fewer than 3 grams fat per serving" (i.e., the basis of the "low fat" claim). The restaurant may provide information about the nutrient for which the claim is made in various ways, including in brochures. In other words, restaurants need not provide such information on the menu or menu board.

A restaurant making such a claim also would not be required to provide complete nutrition information; its decision to provide nutrient content information about one nutrient does not trigger a requirement to disclose complete nutrition information for that item or meal.

C. Stakeholder Participation

From the outset, FDA asked stakeholders to identify obesity issues that FDA should address. Prior to the creation of the OWG, DHHS convened a round table discussion in late July 2003 (bringing together experts from academia, the health professions, industry, and government) to consider how best to address the obesity issue, as reflected in five questions presented to the round table for discussion (see Appendix C for the five questions). As noted above, DHHS also established a Docket in FDA (Docket No. 2003N-0338) to gather information on this subject.

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 12 of 93

Following the creation of the OWG, FDA provided several opportunities for stakeholder participation: a public meeting on October 23, 2003; a workshop on November 20, 2003, that was co-sponsored and funded by the DHHS Office of the Assistant Secretary for Planning and Evaluation (OASPE); roundtable meetings with health professionals/academicians and consumer groups respectively, on December 15 and 16, 2003; and meetings with representatives of the packaged food and restaurant industries. FDA used these opportunities to solicit public comments on the obesity issue, as reflected in six questions the agency asked (these questions are set out in section VI.A. of this report). FDA used the Docket established in July 2003 (Docket No. 2003N-0338) to gather additional comments; the OWG organized the comments to this docket into a searchable database that informed preparation of this report.

D. The OWG's Work

The remainder of this report reflects the work of the OWG subgroups:

- *Obesity Knowledge Base:* Gathered information on existing obesity, weight management, and nutrition related programs.
- *Messages:* Identified existing obesity-related messages in the public and private sectors; conducted focus groups to test five messages; recommended a calorie focus for FDA's action plan.
- *Education:* Explored and is initiating a number of new and enhanced private and public sector partnerships to focus on obesity education.
- Food Label: Explored options for enhancing the food label in relation to efforts to address obesity.
- *Restaurants/Industry:* Explored options for providing consumers with nutrition information on food consumed outside the home; considered the potential health consequences of using diet plans and related products.
- *Therapeutics:* Surveyed existing therapies for mitigating obesity; recommended next steps for updating the 1996 draft guidance entitled "Guidance for the Clinical Evaluation of Weight-Control Drugs."
- *Research:* Identified gaps in obesity knowledge and areas for further biomedical and social sciences research.
- *Stakeholder Investment:* Held meetings and a workshop to solicit stakeholder views; and organized the comments to Docket No. 2003N-0338 into a searchable database that informed preparation of this report.

III. Messages

The Commissioner charged the OWG to set out specific means for developing and implementing a "clear, coherent, and effective FDA message (within the broader context of DHHS) that will unify various public and private efforts to reverse the current obesity epidemic." This part of the charge was expanded with an eye toward establishing a broader theme that focuses on calories (8) as a fulcrum for further action, in the context of an overall healthful diet as defined by the DHHS/USDA *Dietary Guidelines for Americans*.

A. Obesity Knowledge Base

Prior to considering obesity messages and to ensure that it was aware of the range of current public and private efforts to address obesity, the OWG formed a subgroup to collect information on existing and planned obesity-related activities in the United States; assemble a centralized repository of the information gathered; and report out to the full OWG on the scope/contents of the repository.

A majority of the activities listed in the repository and database are programs that provide advice on nutrition/diet and/or physical activity. Most associations, agencies, and organizations identified are sending out the message that diet and physical activity should be addressed together in the fight against obesity.

Many partnerships or collaborations exist between government agencies and/or private entities. There are several areas, however, where different groups manage similar programs. These similar programs, if merged into a larger partnership, could have a greater impact.

To determine whether various programs, activities and initiatives are effective in reducing and/or preventing overweight and obesity in the United States, program evaluation must improve. In addition, improvements are needed in educational outreach to convey the messages and implement the initiatives that government and non-government entities have developed.

B. Obesity Messages

Message Recommendation Highlight:

• Develop messages tied to a "calories count" focus

The OWG formed a subgroup to identify existing messages in the public and private sectors and to set out specific means for developing simple, clear, coherent, and effective FDA messages around the theme of "calories count" based on the scientific fact that net calorie gain or loss over time is the root cause of obesity.

1. Identifying Existing Messages

Today, consumers are inundated with a range of messages about food. Some of these messages are in the form of food advertisements or marketing efforts that focus on product convenience, taste and value. Other messages relate to weight-loss programs or products, or weight management. Some of the messages in each of these areas may not necessarily direct consumers toward wise dietary choices.

The Federal government tries to provide long-term sound nutrition advice to consumers (e.g., government-sponsored public health campaigns). For example, DHHS collaborates with the USDA to establish and promote the *Dietary Guidelines for Americans*, which provide guidance on choosing a lifestyle that combines sensible eating with regular physical activity. An important recent effort of DHHS is *Steps to a HealthierUS*. In support of the President's *HealthierUS* initiative, the DHHS effort emphasizes personal responsibility for the choices Americans make to ensure that policy makers support prevention programs that foster healthy behaviors.

2. FDA Focus Groups on Obesity Messages

Box 2 - FDA Focus Groups

FDA conducts its own consumer research to evaluate the appropriateness and effectiveness of its messages. For example, FDA conducted consumer research before the implementation of NLEA, to determine the usefulness of potential choices for the NFP format. Since NLEA, FDA and other researchers have studied how consumers use the NFP, nutrient content claims, and health claims (separately and in combination) to make dietary choices.

Consumer research is used to assess people's knowledge, attitudes, perceptions, and preferences for a topical subject area or reactions to any type of stimuli. Research methods may include qualitative studies, such as focus groups; quantitative, nationally representative surveys, using structured questionnaires; experimental studies of consumer responses to labeling and package variations; and intervention studies of the effects of point of purchase labeling.

In November-December 2003, FDA, with OASPE funding, conducted focus group research. There were 8 groups of 7-10 participants. Groups were segregated by gender and education level. All participants were at least 18 years old, had been grocery shopping and had eaten in a fast food and/or quickservice restaurant in the past month. The purpose of the groups was to explore (1) how consumers use the nutrition information on food labels; (2) what type of nutrition information they would like to see in quickservice restaurants; and (3) which messages would be effective as part of a public information and education effort aimed toward encouraging consumers to use the food label. Participants discussed and reacted to variations in the NFP and the principal display panel (PDP) on food packages and to various presentations of nutrition information at restaurants.

It is important to emphasize that the findings from these focus groups are based on qualitative research with small sample sizes. They should not be viewed as nationally representative or projectable. Quantitative experimental data are necessary to make reliable and verifiable conclusions. However, these focus group results shed some interesting light on the complex issues discussed in this report and are useful in identifying quantitative research needs.

The focus group findings discussed in this report are preliminary and are based on observations recorded by the observer, as well as post-group discussions with the focus group moderator and other observers.

In November and December 2003, FDA focus groups were convened to evaluate, among other things: (1) how consumers use the nutrition information on food labels; and (2) which messages would be effective as part of a public information and education effort aimed toward encouraging consumers to use the food label (see

Appendix G for FDA Division of Market Studies report, referenced in this report as FDA, 2003). (11) Appendix H contains a discussion on the development of effective consumer messages. The findings from the FDA focus group efforts are discussed below.

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 15 of 93

FDA developed five NFP-based messages that the agency tested through its focus groups. The messages and materials were intended to remind people where to find the NFP, why it is there, and how to use the information; while at the same time reinforcing various "promises" (i.e., motivators) associated with regularly using the NFP.

The messages tested were as follows:

- 1. "Read it before you eat it Always look at the Nutrition Facts"
- 2. "Calories count and fat matters Always look at the Nutrition Facts"
- 3. "Do you know the serving size? Always look at the Nutrition Facts"
- 4. "What you eat is what you are Always look at the Nutrition Facts"
- 5. "If you read labels for things you put *on* your body, why wouldn't you read labels for what you put *in* your body?"

Overall, none of these "slogan-type" messages resonated particularly well with the FDA focus group participants. Nevertheless, FDA focus group participants believed that reminder messaging about the NFP would be helpful. In addition, the results of other focus groups indicate that messaging should emphasize small, incremental steps versus major life changes with respect to weight management and obesity prevention, and should address the importance of "planning ahead" as a necessary step for eating right (Borra *et al.*, 2003; IFIC, 2003).

C. OWG Message Recommendations

The OWG recognizes that some focus group (Borra *et al.*, 2003; FDA, 2003; IFIC, 2003) and some quantitative data (Derby and Levy, 2000; Levy, 2004; Lin, 2004) indicate that not all consumers pay enough attention to calorie information in the NFP. Nevertheless, given the fact that obesity, at its most fundamental level, is a direct function of caloric imbalance, the OWG believes that "calories count" must be the focus for its recommendations. Accordingly, in relation to messages, the OWG recommends the development and testing of messages tied to this focus.

IV. Education Program to Deliver the Message

Education Recommendation Highlight:

• Establish partnerships to educate Americans about obesity and leading healthier lives through better nutrition.

The Commissioner directed the OWG to outline an FDA program (component of DHHS program) for educating Americans about obesity and the means to prevent chronic diseases associated with it.

A. Need for Education Programs

Consumer perceptions regarding weight and dietary habits are significant in the fight against the obesity

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 16 of 93 epidemic. Consumers who are not aware of their own weight status and its medical implications are unlikely to be receptive to public health efforts to alleviate obesity. This point extends to parental perceptions of children's weight status and dietary habits as well, given that parents have significant influence over their children's environment, habits, and health. Lack of knowledge about weight status and its health implications undermine consumers' "promise" or motivation, a key component of messaging; therefore the OWG identified education as a critical adjunct to effective messaging about caloric balance.

Recent focus group studies conducted by the International Food Information Council (IFIC)⁽¹²⁾ suggest that consumers distinguish between "overweight" and "obesity," and consider the first to be of relatively little health significance (IFIC, 2003). Therefore, consumers who consider themselves to be merely "overweight" may have less incentive to take action. There is also evidence to suggest that both adults (Kuchler and Variyam, 2003) and teenagers (Kant, 2002) misperceive their weight status, although the form of misperception can vary with gender, socioeconomic status, age and race and ethnicity. For example, men were found to be more likely than women to underestimate the level of their weight status; healthy or underweight women were more likely to consider themselves overweight. Lower income and education were also associated with underassessment of weight status; higher income and education levels were linked to overestimation of weight status. Parents also appear prone to misjudge their children's weight status and its health significance (Borra *et al.*, 2003; Contento *et al.*, 2003; Maynard *et al.*, 2003). Many parents with overweight children consider their children to be at a healthy weight. In some cases this may be due to cultural perceptions of appropriate weight (Bruss *et al.*, 2003; Contento *et al.*, 2003). In some cases where parents do accurately judge their children's weight status, they may believe that the child will outgrow their overweight or obese status and, therefore, be less likely to take action.

Consumers may have difficulty accurately assessing the nutritional quality of their diet. Although consumers report in focus group studies that they understand what comprises a healthy diet (IFIC, 2003), approximately 40 percent of one sample (almost 3000 household meal preparers drawn from USDA 1994-1996 Continuing Survey of Food Intakes by Individuals (CSFII) data) perceived the quality of their diets to be better than the calculated diet quality (Variyam *et al.*, 2001). Parents, in particular, do not always have a clear picture of their children's diets. In a recent series of focus groups and phone/Internet surveys conducted by the American Dietetic Association Foundation (Moag-Stahlberg *et al.*, 2003), parents significantly underestimated the frequency with which children ate outside of regular mealtimes, such as after dinner and while engaged in sedentary activities like television viewing. A recent report by the Kaiser Family Foundation discusses the role of media in childhood obesity (KFF, 2004).

Qualitative research by Borra and colleagues (Borra *et al.*, 2003) also suggests that children (aged 8-12 years) give little thought to good health, although they associate achieving "good health" with what they eat, rather than with physical activity. For many of the children involved in the research by Borra and colleagues, the term "healthy" had negative connotations; for example, it meant having to eat fruits and vegetables they did not like or not eating their favorite foods. In terms of weight, children between 8 and 10, regardless of their own weight, did not think about food choices. Equally disturbing, some 11-12 year olds who were overweight said they tried to lose weight by skipping meals, rather than by eating differently. Among a group of children perceived to be above normal weight for their age, Borra and colleagues found that although the children knew it was important to eat healthfully because their parents stressed it at home and they learned about nutrition in school, this teaching provided little useful information for the children.

These qualitative findings are supported by a recent unpublished survey conducted for the nonprofit Dole Nutrition Institute of more than 6,000 children between grades 1-8 in 194 classrooms (Dole, 2003). The responses to survey questions "What is obesity?" and "Which statement is true [about being overweight]?"

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 17 of 93 indicate that many children seem to have either misperceptions or are misinformed about (1) the meaning of obesity and (2) the value of exercise in preventing or mitigating health problems due to overweight.

B. OWG Education Recommendations

The OWG recommends that FDA focus its education strategy on influencing behavior, as well as imparting knowledge, in the context of healthy choices for consumers. Any such efforts will require a long-term agency commitment. Education programs should help consumers make more informed food choices that result in better weight management; should direct messages to large audiences on a frequent basis; and should be crafted to reach a variety of audiences.

The OWG recommends that FDA implement education programs incrementally and design them to be flexible enough to take into account new research findings and policy decisions and possible changes in the food label (e. g., revisions to the content or format of the NFP). Education efforts, however, should not be delayed pending such changes. Education programs should be simple to understand and apply, and should focus on showing consumers how to achieve a specific goal.

Given the resources and time that FDA would need to develop and implement new education programs for multiple subpopulations, the OWG recommends that FDA, as part of a larger DHHS initiative, establish relationships with private and public sector partners for educational outreach. Such efforts will have the ability to reach larger and more diverse audiences on a more frequent basis, and will enable calorie-focused education campaigns to begin more quickly. Given the prevalence of obesity among children, establishing relationships with youth oriented organizations is especially important. For this reason, the following partnerships are being pursued as a part of a larger DHHS initiative:

- **Girl Scouts of the USA :** FDA and Girl Scouts of the USA seek to launch an initiative entitled "Healthy Living." Building on current Girl Scout resources and programs, the initiative will provide girls and their families with the skills, knowledge, and support needed to make healthier food choices, engage in physical activity, build self-esteem, and maintain a healthier lifestyle. This initiative includes developing a charm of the food label as a part of the Studio B teen collection.
- National Association of State Universities and Land Grant Colleges (4-H program): Youth health and obesity is one of three strategic priorities for 4-H Youth Development. FDA envisions a partnership that will use 4-H for targeted population evaluation of obesity/nutrition message(s), and use the 4-H network of over 3,500 professional Cooperative Extension programs across the United States for education and delivery of the message(s).

In addition, FDA, along with other components of DHHS, is participating in the "Shaping America's Youth" initiative to identify actions being taken to address childhood and adolescent inactivity and excess weight. Information collected for this initiative in an on-line survey will be used by "Shaping America's Youth" to prepare a report that provides an overview of current public and private programs that target physical activity and nutrition in our nation's children. As of the date of this report, Shaping America's Youth has registered over 1950 programs directed at the childhood obesity issue, collected surveys of funding and tactical information from over 1150 organizations and entities, and assembled nearly 800 fully completed in-depth surveys from programs representing all 50 states and the District of Columbia.

Public sector partnerships should have the goal of developing programs similar to the "Power of Choice" program FDA developed with the USDA, which teaches children who are 11-13 years of age how to make

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 18 of 93 smart food and physical activity choices in real-life settings. Learning how to use the NFP to make healthy food decisions is a major skill throughout the "Power of Choice" program (see Appendix I for additional information about "Power of Choice"). One way to help better ensure collaboration and cooperation with our public health partners is for FDA to coordinate its messages and educational material with those of its partners.

- Centers for Disease Control and Prevention: FDA is pursuing a collaboration between the agency and the CDC to develop a holistic approach to healthy living for children that will enable the FDA to meld a caloric intake message with a CDC caloric output message on physical activity.
- **Department of Education:** FDA has made preliminary contact with the Department of Education to join in supporting programs that target school-age children.
- **Department of Agriculture:** FDA plans to work through DHHS with counterparts at USDA to ensure that the agency's focus on calories is considered as USDA revises its Food Stamp Program/WIC (Women, Infants, and Children) programs and its Food Guide Pyramid, and as DHHS and USDA collectively revise the *Dietary Guidelines for Americans*.

The OWG recommends that FDA work through a facilitator to establish a forum for stakeholders to seek consensus-based solutions to specific aspects of the obesity epidemic in the United States, with a particular focus on the needs of children. As a first step, the OWG further recommends that the initiation of such a dialogue be raised at the next meeting of the FDA Science Board.

V. Supporting the Message

It is important to support any message(s) through appropriate actions and policies where the "calories count" focus is likely to have an impact on consumer knowledge, behavior, and/or treatment (i.e., food labels, restaurants, therapeutics, and research).

A. Food Labels

Food Labeling Recommendation Highlights:

- Calories:
 - o Issue an ANPRM to solicit public comment on how to give more prominence to calories on the food label.
 - o Consider authorizing a health claim on "reduced" or "low" calorie foods.
 - Issue an ANPRM about serving sizes.
- Serving Sizes:
 - Encourage manufacturers immediately to take advantage of the flexibility in current regulations on serving sizes and label as a single-serving those food packages where the entire contents can reasonably be consumed at a single-eating occasion.
 - Highlight enforcement of serving sizes in FDA's food labeling compliance program and consider enforcement action against products that declare inaccurate serving sizes.

- Carbohydrates:
 - File petitions and publish a proposed rule to provide for nutrient content claims related to carbohydrate content of foods, including guidance for use of the term "net" in relation to the carbohydrate content of foods.
- Comparative Labeling Statements:
 - Encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to make healthy substitutions, including calories (e.g., "instead of cherry pie, try our delicious low fat cherry yogurt - 29 percent fewer calories and 86 percent less fat").

The Commissioner directed the OWG to "develop an approach for enhancing and improving the food label to assist consumers in preventing weight gain and reducing obesity."

1. The Food Label

The Act, as amended by the NLEA, and FDA's implementing regulations require an NFP on the label of most packaged foods. The NFP lists the serving size, the number of servings per container, the number of calories per serving and the amount and $%DV^{(13)}$ per serving for specified nutrients.

Before recommending any changes in the NFP relevant to obesity, it is important to understand how consumers currently use the NFP and to assess whether the NFP has been effective in facilitating positive dietary change. Research shows that most consumers are familiar with the nutrition information on food labels (Marietta *et al.*, 1999; Neuhouser *et al.*, 1999; Kristal *et al.*, 2001; FDA, 2003), which they use primarily for evaluating the nutrition quality of specific food products, but the percentage of consumers who use NFP information productively for weight management purposes is low (Barone *et al.*, 1996; FMI, 1996; Ford *et al.*, 1996; Levy *et al.*, 1996; Mitra *et al.*, 1999; Roe *et al.*, 1999; Garretson and Burton, 2000; Levy *et al.*, 2000; IOM, 2003; FDA, 2003) (e.g., see Table 1 below).

Table 1. Recent Trends in Reported Food Label Use: 1994-2002 HDS Surveys(Derby and Levy, 2000; Levy, 2004; Lin, 2004)

	1994	1995	2002		
Sample size (N)	(1,945)	(1,001)	(2,743)		
	% population (weighted)	% population (weighted)	% population (weighted)		
(1) Percent who use food labels "often" or "sometimes" when buying a food product for the first time					
How often do you read the food label?	70	69	69		
(2) Percent who use labels "often" for specific purposes ¹					

Case 1:08-cv-01000-RJH Document 33-6	Filed 02/15/200	8 Page 20 of 9	93		
To figure out how much to eat	34	40	35		
To see if food is high or low in calories, salt, vitamins, fat, etc.	77	83	67		
To help in meal planning	34	36	32		
(3) Percent who use specific label information "often" ²					
Do you use the serving size information, when available?	29	26	Not Asked		
1 D 1 - 1 1 - 1 - 1 1 - 1					

¹ Based only on label users who "often" or "sometimes" use labels when they buy a food product for the first time.

Associations between dietary behavior and food label use have also been identified, although the body of literature is relatively small (IOM, 2003). A low-fat diet, for example, has been positively correlated with food label use, both in the general population and among family clinic patients. Clinic patients with health conditions (e.g., high blood pressure or high cholesterol) as well as consumers who are in action or maintenance stages of dietary change were also more likely to use the food label (Kreuter *et al.*, 1997; Marietta *et al.*, 1999; Neuhouser *et al.*, 1999; Kristal *et al.*, 2001). In addition, label claims (e.g., low sodium and low fat) may allow consumers to avoid specific ingredients or make food substitutions (Balasubramanian and Cole, 2002), resulting in changes to dietary patterns. Kim and coworkers (Kim *et al.*, 2001) analyzed data from the USDA's CSFII and the Diet and Health Knowledge Survey. Their findings indicate that food label use is positively correlated with measurable increases in the Healthy Eating Index (Kim *et al.*, 2001). (14)

Despite reports of a positive correlation between label use and certain positive dietary characteristics, the trend toward obesity has accelerated over the past decade. It may be that consumers do not take advantage of the available information on the food label to control their weight, perhaps because they do not appreciate how the information could be used for weight management purposes or perhaps because they find it too hard to apply the available information to such purposes. In any case, it is clear that consumers would benefit if they were to pay more attention to and make better use of information, including calories, on food labels. Providing encouragement and making it as easy as possible for consumers to do so are worthy public health objectives.

2. FDA Focus Groups on Food Labels

As described in Box 2, FDA recently conducted focus group research in which it asked general nutrition questions as well as how consumers use the nutrition information on food labels.

The questions covered under general nutrition dealt with three topics: (1) attitudes towards nutrition; (2) macronutrients; and (3) %DV. Those covered under food label modification dealt with six topics: (1) large package sizes; (2) serving versus package; (3) calorie-related variations; (4) serving size variations; (5) calorie cues; and (6) "healthier" symbol. For additional information on FDA's focus group findings, see Appendix G.

Attitudes towards nutrition. In many of the groups, especially the women's groups, participants cared about nutrition and report using the NFP. At the same time, however, many also said that they do not always consider

²Based on all respondents.

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 21 of 93 nutrition when deciding what to eat. Taste, convenience, price, what kind of mood they are in, and what their family eats were often at odds with healthy eating. Although participants were interested in calories, many pointed to multiple concerns that went beyond calories such as the level of saturated fat, total fat, cholesterol, carbohydrates and sodium. Many participants reported not wanting to spend a lot of time reading labels.

Macronutrients. In general, individual participants tended to care more about some macronutrients than others, depending on their individual dietary practices. In most groups, at least one participant was familiar with the Atkins diet and many of these participants were most concerned about carbohydrates and sugars. Others were concerned about fat and saturated fat. Some participants checked the NFP mostly for information about sodium. Those who were on the Weight Watchers diet were concerned about calories and fiber.

%DV. Very few participants reported using the %DV column on the NFP. Either they did not understand the meaning of %DV or they thought that it was not relevant to them since they did not consume a 2000 calorie diet. Those who did use or might use %DV thought that is was a good way to estimate how much of a particular nutrient they were eating or to gauge a healthy and balanced diet.

Large package sizes. In all the groups, participants were presented with a mock-up label of a 20 ounce soda and a large packaged muffin. Both of these products are thought to be commonly consumed in one sitting, but have more than one serving listed.

Serving versus package. In general, participants thought it was misleading to list either product as having more than one serving. Many participants did realize that if the entire package is eaten, the number of servings should be multiplied by the amount of the nutrient of interest, though some participants were confused and made mistakes when trying to calculate the total amount in their heads.

Calorie-related variations. The first test label added a %DV for calories, removed the calories from fat line, enlarged the calories line, and changed the way serving size was declared. In general these changes were not noticed by participants. When the new wording for serving size was pointed out, most participants did not think it was an improvement over the existing language.

Serving size variations. The second test label had two %DV columns on the NFP, one for a specified serving size and one for the entire package. In the first four groups, the absolute quantities of macronutrients were only listed for the specified serving size. After comments from these groups, the label was modified to have the absolute amount for both the specified serving size and the entire product. Participants reacted positively to this modification, but some thought it was not necessary to list the amount for a specified serving size.

Calorie cues. Both a "starburst" with the calories per serving and a white square with calories per whole product on the package's PDP were tested. Many participants thought that the starburst was misleading because they thought the manufacturer was trying to indicate the entire product had fewer calories than it did. The white square with the total calories per product got mixed reactions, but many participants just said that they recognized these as high calorie products and would stay away from them.

"Healthier" symbol. Half of the groups tested a "healthy" meat lasagna with a purple keyhole symbol on the PDP. There was generally positive reaction to including a front-of-package symbol indicating that a product was "healthy," as long as participants understood the definition of the symbol and could trust that it was true. Participants believed that they would have to be educated as to the meaning of such a symbol. Some participants mentioned that they would look for the symbol when they were in a hurry in the store. They expressed some

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 22 of 93 concern that these products would cost more or that they would lack in taste.

3. OWG Food Label Recommendations

The OWG recommends that FDA (1) develop options for revising or adding caloric and other nutritional information on food packaging (examples provided below); (2) obtain information on the effectiveness of these options in affecting consumer understanding and behavior relevant to caloric intake; and (3) evaluate this information to make evidence-based decisions on which option(s) to pursue.

a. Calories and Serving Sizes

In light of the critical importance of caloric balance in relation to overweight and obesity, the OWG recommends that FDA: (1) solicit comment on how to give more prominence to calories on the food label; (2) consider authorizing a health claim on "reduced" or "low" calorie foods; and (3) reexamine the agency's regulations about serving size.

Solicit comments on how to give more prominence to calories on the food label. Many of the written and public comments submitted to the agency suggested that FDA develop ways to emphasize calories on the food label. To address this, the OWG recommends that FDA publish an ANPRM requesting comments on how best to give more prominence to calories. Possible changes to the NFP include: (1) increasing the font size for calories; (2) providing for a %DV for calories; (3) eliminating "calories from fat" listing as this takes the emphasis away from "total calories;" and (4) increasing the font size for serving size in order to give it more prominence.

Consider authorizing a health claim on "reduced" or "low" calorie foods. A number of comments submitted to the agency, including those from the FTC, suggested that FDA permit health claims on reduced calorie foods as a way to reduce the risk of certain chronic diseases associated with obesity, such as diabetes, coronary heart disease and cancer. To address this suggestion, the OWG recommends that FDA publish an ANPRM on whether to allow a health claim such as "Diets low in calories may reduce the risk of obesity, which is associated with diabetes, heart disease, and certain cancers" on certain foods that meet FDA's definition of "reduced" or "low" calorie. In addition, the OWG recommends that FDA encourage manufacturers to use dietary guidance statements (e.g., "to manage your weight, balance the calories you eat with your physical activity; have a carrot, not the carrot cake; and as a snack have an apple rather than a serving of potato chips").

Reexamine the agency's regulations on serving sizes. The comments that FDA has received at its public meetings and to the docket (including comments from the FTC) express concern about the serving sizes used in nutrition labeling, particularly on packaged products that can readily be consumed at one occasion but that indicate they represent more than one serving. To address this issue, the OWG recommends the following:

- In the short-term, that FDA encourage manufacturers immediately to take advantage of the flexibility in current regulations on serving sizes (21 CFR 101.9(b)(6)) that allows food packages to be labeled as a single-serving if the entire content of the package can reasonably be consumed at a single-eating occasion.
- In the long-term, that FDA develop two separate ANPRMs. The first would solicit comment on whether to require additional columns within the nutrition label to list the quantitative amounts and %DV of the entire package on those products and package sizes that can reasonably be consumed at one eating occasion or, alternatively, declare the whole package as a single serving. This ANPRM would also solicit information on products and package sizes that can reasonably be consumed at one eating occasion. The

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 23 of 93 second ANPRM would solicit comments on which, if any, RACCs of food categories appear to have changed the most over the past decade and therefore need to be updated.

The serving size is critical to nutrition labeling since all of the information on nutrient levels depends on the amount of the product represented. By statute, the serving size is to be based on the "amount [of the food] customarily consumed" (section 403 of the Act). Accordingly, when implementing NLEA, FDA reviewed food consumption data obtained from USDA's 1977-78 and 1987-88 Nationwide Food Consumption Surveys and, based on the results of that review, established RACCs for 139 food categories (58 FR 2229, January 6, 1993). Inasmuch as there is evidence that Americans are eating larger portions than they did in the 1970s and 1980s, the OWG recommends that FDA determine whether and, if so, how to update RACCs.

The accuracy of the information in the NFP is crucial for consumers who use this information to monitor their intake of calories and nutrients. Current enforcement efforts targeted at the NFP as described in FDA's Food Labeling Compliance Program are directed at ensuring that actual nutrient levels are within 20% of declared values. More limited resources have been directed at ensuring that serving sizes are calculated and declared accurately. Comments and other information submitted to FDA express concern about the inaccuracy of serving size declarations used in nutrition labeling and reiterate the importance of accurate serving size declarations because all of the information on nutrient levels is dependent upon the amount of the product represented. To address this issue, the OWG recommends that FDA highlight enforcement of serving sizes in the Food Labeling Compliance Program by April 2004, and consider enforcement activities against those products that declare inaccurate serving sizes.

b. Carbohydrate Labeling

Today there is increasing interest in low carbohydrate diets (see text box on Carbohydrates and Other Macronutrient Contributions to Caloric Value in Appendix B). FDA has recently received petitions requesting that the agency provide for nutrient content claims related to the carbohydrate content of foods. Claims for carbohydrate content of foods have become increasingly common in the marketplace while, at the same time, the level of carbohydrates in foods marketed under the various carbohydrate claims appears to vary widely. In order to ensure that terms are consistently defined and that carbohydrate claims are not false or misleading, the OWG recommends that FDA file these petitions and publish a proposed rule to provide for nutrient content claims related to the carbohydrate content of foods, including guidance for the use of the term "net" in relation to carbohydrate content of foods.

c. Other Labeling Issues

The OWG considered comments from the FTC on the issues of (1) reduced/fewer calorie comparisons, (2) comparison to food of different portion size, (3) comparison to food of different product type, and (4) disclosure requirements for comparative claims.

Reduced/fewer calorie comparisons. The underlying principle for FDA's regulation is that reductions be **significant** compared to the reference food (21 CFR 101.60(b)(4). FDA determined that percentage reductions less than 25% were too small to be meaningful because of normal product variability. Such variability may be caused by factors such as: natural nutrient variability of the food due to season of the year, soil type, variety, and weather conditions; variability in processing; rounding rules (e.g., rounding to the nearest 5 calories up to 50 calories and to the nearest 10 calories above 50 calories); analytical variance (ranging from +/- 3-4% to +/- 30 %

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 24 of 93 with an average variance of about +/- 15%); sampling procedures; and shelf life and stability of nutrients in the product.

As a result, 21 CFR 101.9(g) allows for a 20% excess in the actual (analytical) nutrient content of calories, sugars, total fat, saturated fat, cholesterol or sodium of a product compared to the declared nutrient values for that product (and consequently the qualifying values for nutrient content claims) before the food is considered to be misbranded. Therefore, nutrient reductions less than 25% are virtually within the allowable product variability and are not considered significant. The minimum absolute reduction (e.g., equivalent to the value of "low") was changed to permit claims compared to reference foods that were not already "low" in the nutrient because it was the agency's conclusion that benefits derived from several servings of nutritionally modified nutrient dense foods over a day could have a significant impact provided that the reduction was significant, i.e., 25% or more. FDA further concluded foods already "low" in that nutrient were below the level at which the amount of nutrient in the food becomes significant relative to the total diet and therefore should not be used as reference foods.

For relative claims, the OWG notes that the Codex Alimentarius Commission (17) requires that there be a difference of at least 25% in energy value or nutrient content (except for micronutrients where a 10% difference in the nutrient reference value would be acceptable) with a minimum difference between the compared foods equivalent to a "low" value (FDA's proposed requirements for "less"). Moreover, Canada requires that comparative claims be based on differences which are both nutritionally and analytically significant. (18) Canadian regulations consider reductions of less than 25% from the reference value to be of questionable nutritional significance. Canada does not allow claims on reductions of less than 25%.

The OWG recommends the agency be receptive to such a claim, if the proponent of such a claim is able to provide data and information to substantiate that:

- 1. The claim is not misleading due to the known variations in food composition and analytical methods, and
- 2. The claimed reductions are nutritionally significant.

Comparison to food of different portion size. FTC has suggested that FDA consider "allowing food marketers to make truthful non-misleading label claims comparing foods of different portion sizes." FTC provided the example of a 10 oz chicken and rice casserole labeled as having 33 percent fewer calories than 15 oz. of the same chicken and rice casserole.

Consuming a smaller portion size of the same food simply decreases caloric consumption proportionally. To enable consumers to make meaningful comparisons for calorie reduction, FDA requires such claims to be based on the amount per RACCs, or per 100 gram in the case of meal-type products. Thus, under FDA's current regulations (21 CFR 101.60(b)), a comparative calorie claim of the type that FTC proposes would not be allowed.

Nevertheless, using the food label to promote consumption of smaller portions may have merit. This is especially true if consumers understand that (a) the calorie reduction is solely a function of the reduction in portion size, and (b) that the smaller portion size is actually less than what they usually consume. Thus, the OWG recommends that FDA issue an ANPRM to solicit comments on truthful non-misleading and useful approaches for promoting consumption of smaller portion sizes, including FTC's suggestion.

Comparison to food of different product type (which the OWG refers to as comparative labeling statements). FTC suggests that FDA "consider allowing food companies to make label claims that compare the calories of foods [across] different product categories." FTC points out that switching from one category to another category often can be an effective means of reducing calories, such as substituting carrot sticks for potato chips or fruit for cookies. FTC notes that comparative caloric claims across categories could help consumers make these healthy substitutions. FTC offered as an example, "instead of cherry pie, try our delicious low fat cherry yogurt - 29 percent fewer calories and 86 percent less fat." (19)

Current FDA regulations do in fact permit certain comparative claims. In addition to the example that FTC provided, the OWG offers the following as examples of comparative claims that are permissible under current regulations:

- One medium apple (80 calories) contains 47% fewer calories than a one ounce serving of potato chips (150 calories).
- Carrots have 93% fewer calories than carrot cake. One 7-inch carrot (78 g) contains 35 calories while one slice of carrot cake with icing (125 g) contains 500 calories.
- Air-popped popcorn (without added toppings) contains one-half the calories of a plain granola bar (98 calories per 3-cup serving of popcorn, 200 calories per 1.5 ounce granola bar).

The OWG recommends that FDA encourage manufacturers to use appropriate comparative labeling statements that make it easier for consumers to make healthy substitutions, including calories. Such comparisons provide valuable information that can be used in making food choices. Moreover, there is a flexible standard for product categories that is intended to facilitate useful comparisons for foods that are generally interchangeable in the diet (for example, "apples have less fat than potato chips") while prohibiting meaningless or misleading claims (58 FR 2302 at 2363, January 6, 1993). Manufacturers have to use judgment in developing claims to ensure that the claims comply with the regulations and are not false or misleading under section 403(a) of the Act.

Disclosure requirements for comparative claims. FTC suggests that FDA "evaluate whether unnecessarily cumbersome disclosure requirements have deterred truthful, non-misleading comparative label claims for foods." As always, FDA is open to dialogue on such an issue, particularly when a proposal is supported by relevant data and information.

To make a comparative nutrient claim, a food marketer must provide information on the reference food, the percentage by which the nutrient in the reference food has been changed, and the absolute amount of the nutrient in the labeled and reference food (21 CFR 101.13(j)(2)). The agency, however, is not wholly prescriptive as to the actual words used or where all the information is placed on the label.

FTC offered as an example, a baked potato chip that is lower in both calories and fat than a regular potato chip, and indicated that label claims explaining the benefits would be awkward to place (and read) on the front panel. According to FTC, under FDA regulations, the claim would read as follows (italicized phrases may be placed on the back nutrition label):

"Reduced fat and fewer calories than our Classic Potato Chips. Fat reduced by 85 percent, from 10 grams per ounce to 1.5 grams per ounce. Calories reduced by 27 percent, from 150 calories per ounce to 110 calories per ounce."

The OWG notes that the FTC example could be more succinct. As FTC suggests, more than 50% of the text may be placed on the back nutrition label. Beyond that, under FDA's current regulations (21 CFR 101.13(j)), the PDP could simply read:

85% less fat and 27% fewer calories than our Classic Potato Chips.

B. Restaurants/Industry

Restaurants/Industry Recommendation Highlights:

- Short-term
 - Urge restaurant industry to launch a nation-wide, voluntary, and point-of-sale nutrition information campaign for consumers.
 - Encourage consumers routinely to request nutrition information in restaurants
- Long-term
 - Development of a series of options for providing voluntary, standardized, simple, and understandable nutrition information, including calorie information, at the point-of-sale to consumers in restaurants.
 - FDA to seek participating restaurants for a pilot program to study these options in well controlled studies
 - FDA to provide incentives, if necessary, for voluntary industry participation in the pilot program.
 - FDA to evaluate results of the pilot program to determine whether further research is warranted before such a program is implemented on a large scale.
 - Exploration of the concept of third-party certification of weight-loss diet plans and related products.
- Enforcement
 - o Together with the FTC, increase enforcement against weight loss products having false or misleading claims.

The Commissioner directed the OWG to "develop an approach for working with the restaurant industry to create an environment conducive to better informed consumers."

In light of the growing proportion of American meals consumed outside of the home, it is important to enlist the assistance and support of restaurants in addressing population obesity. Since the late 1990s and projecting through 2004, American households are spending approximately 46 percent of their total food budget on food consumed outside the home (ERS, 2003; NRA 2004). During 1994-1996, food consumed outside the home, especially from restaurants and quickservice food establishments, contributed 32 percent of daily intakes of energy calories, 32 percent of added sugars, and 37 percent of fat (ERS, 2000). Thus, food consumed away-

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 27 of 93 from-home is an important part of American diets and more informed dietary choices away-from-home could help reduce calorie over-consumption and the risk of obesity and its associated health problems.

The distribution of meal sources has also shifted over the past few decades, and this shift may be another significant factor in weight gain. Food consumed outside the home has increased from approximately 33 percent of U.S. consumers' food budget in 1970 to approximately 47 percent as of 2002 (ERS, 2003; Young and Nestle, 2002). Over a similar period, total calories from food consumed outside the home, especially from quickservice restaurants, increased from 18 percent to 32 percent. In addition, food consumed outside the home was higher per meal in calories, total fat and saturated fat, as well as was lower in fiber, calcium and iron on a per-calorie basis (Guthrie *et al.*, 2002).

As noted above, under the laws administered by FDA, restaurants are not required to provide nutrition information unless a nutrient content or health claim is made for a food or meal. When claims are made, however, the restaurant need only provide information about the amount of the nutrient that is the subject of the claim. Restaurants may, and many do, provide nutrition information on a voluntary basis. Nevertheless, this nutrition information is often in the form of posters, placemats or menu icons, or on the Internet; rather than at the point-of-sale. Such information is not always readily available or observable at the point-of-sale.

1. FDA Focus Groups on Restaurants

As described in Box 2, FDA recently conducted focus group research in which it asked questions about what type of nutrition information participants would like to see in quickservice restaurants. Participants discussed and reacted to various presentations of nutrition information at restaurants. The questions dealt with four topics: (1) nutrition information; (2) menu board information; (3) menu board section; and (4) "healthier" symbol. For additional information on FDA's focus groups, see Appendix G.

Nutrition information. Most participants seemed interested in having nutrition information available to them when they eat at fast food and/or quickservice restaurants, though they might not use it every time they eat out. Participants suggested that this information could be presented in many locations in the restaurant including food wrappers, tray liners, brochures, on the take-away bags, posters near the counter, and the menu boards.

Menu board information. Participants reacted to multiple versions of a menu board for a typical fast food restaurant. In general, participants liked having calories listed after meal items and after combo meals. Those who tend to order *a la carte* preferred to have calories listed after each item, while those who usually order a combo meal preferred to have calories listed for the entire meal. Although participants were concerned with multiple macronutrients for foods, having just calories listed was enough for many of them. Participants thought that calories could be a signal for the level of other macronutrients.

Menu board section. Most participants also reacted favorably to the idea of placing healthier options, including meals, in a separate section of the menu board so they could find healthier options at a quick glance.

"Healthier" symbol. Many participants also reacted favorably to a purple keyhole symbol for healthier meals, but some thought that the exact number of calories should be listed as well. Again, the symbol would have to be trusted and consumers would have to understand the meaning of the definition.

2. OWG Restaurant Recommendations

The OWG recommends that FDA encourage restaurants to provide more, and more readily available, nutrient content information at the point-of-sale. The restaurant industry has voiced concern that requiring nutrition labeling for all menu items is infeasible because recipes change frequently, and patrons often request customization of their meals and the number of options available for customization is large. For example, recent National Restaurant Association research indicates that 70% of consumers customize their meals when eating in restaurants. Nevertheless, the OWG believes that the restaurant industry could provide some level of nutrition information to its patrons to enhance their ability to make wise food choices. Calculating nutrition information may have been a difficult task for most members of this industry in the past, when such information had to be determined by direct chemical analysis. This task, however, is easier today because nutrient composition databases and software for labeling are readily available. Possibilities for providing nutrition information to consumers include: segregating "healthier" menu items with simple nutrition information in a separate section of the menu; providing icons for individual "healthier" menu items; and presenting nutrition information in locations in the restaurant where patrons can readily use it (i.e., at the point-of-sale).

The OWG also recommends that FDA encourage consumers routinely to request nutrition information in restaurants. Because restaurants respond to consumer demand (as evidenced by comments made by members of the restaurant panel at the November 20, 2003, workshop), such demand may help create an impetus for more restaurants to provide such information.

The OWG believes that there is a need for research to determine the best way(s) to present nutrient content information to consumers so that they will make healthier choices when eating food away from home. The OWG recognizes, however, that such research will take a substantial period to plan and complete. In the interim, the pervasiveness of the obesity epidemic means that more nutrition information must be presented to consumers in restaurant settings. Accordingly, the OWG has developed both short-term and long-term recommendations

The OWG recommends that in the short-term, FDA urge the restaurant industry to launch a nation-wide, voluntary, and point-of-sale nutrition information campaign for customers.

Over the long-term, the OWG recommends that:

(1) Options be developed for providing voluntary standardized, simple, and understandable nutritional information, including calorie information, at the point-of-sale in a restaurant setting.

Ideally these options should focus on the caloric content and nutritional composition of complete meals rather than individual menu items. Although a focus on total calories is the most useful single piece of information in relation to managing weight, additional information on nutrient content of the meal is also important. This is true, for example, for people with diabetes or coronary heart disease who need to more carefully control their consumption of certain nutrients (e.g., carbohydrates, sodium, fat). An alternative to listing detailed numeric information is to use a graphical representation that conveys the same information using a picture or symbol.

(2) FDA seek participating restaurants for a pilot program to study these options in well controlled studies.

The number of restaurants participating in the pilot program should be large enough to include a variety of locations, cuisines, and average price of menu items. The pilot program needs to be long enough to account for

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 29 of 93 any time required to understand the new menu formats and nutrition information. Participating restaurants would need to provide item-by-item sales data before, during, and after the pilot. Experimental economics methods could substitute partly but not wholly for actual market data to assess the impact of various labeling options on consumer behavior.

FDA could also use this pilot program to explore engaging the restaurant industry as a powerful distribution system for the agency's messages on obesity and its education programs.

(3) FDA provide incentives, if necessary, for voluntary industry participation in the pilot program.

Such incentives could include allowing restaurants to use FDA's name to promote the pilot in advertising, on stickers, and on their menus; and/or coupling the pilot program with an overall FDA education campaign, which may include space on restaurant menus or on separate handouts for FDA messages on healthy lifestyles.

(4) FDA evaluate results of the pilot program.

FDA would need to analyze the results of any pilot program to determine whether further research is warranted before such a program is implemented on a large scale.

In order to pursue these more long-term recommendations, the OWG recommends that FDA work through a facilitator to provide a forum for stakeholders to seek consensus-based solutions to specific aspects of the obesity epidemic in the United States, with a particular focus on food consumed away from home. As a first step, the OWG further recommends that the initiation of such a dialogue be raised at the next meeting of the FDA Science Board.

3. OWG Weight-Loss Diet Plan Recommendations

Just as consumers spend a significant amount of money for foods consumed outside the home, they spend substantial sums on weight-loss diet plans and diet-related products. Such plans and products have the potential to affect all food choices by at least some consumers. The long-term weight or health effects of these and other weight control measures remains unclear (Connors and Melcher, 1993; Ayyad and Andersen, 2000; Saris, 2001; Anderson, *et al.*, 2001; and Phelan, *et al.*, 2003). This raises the question of whether consumers who follow these plans and buy these products understand the health implications, particularly the systematic difficulties of long-term weight management. For these reasons, the OWG also considered the health consequences of using weight-loss diet plans and related products. The OWG concluded that, in the long-term, research needs to be done outside of FDA to determine whether claims for such diet plans and related products have been or can be substantiated. Thus, the OWG recommends that there be an exploration of the concept of third party certification of weight-loss diet plans and related products. The goal is to improve consumer information about the health consequences of their overall dietary choices.

With respect to diet-related products, on December 18, 2002, FDA announced a significant enforcement initiative targeted at misleading claims about dietary supplement-associated health benefits. Dietary supplements are used by an estimated 158 million Americans, and so misleading claims about their health benefits may have significant consequences - not only for wasting consumers' money but also for luring consumers interested in improving their health in wrong directions. Although FDA's enforcement goals related to truthful and non-misleading statements about health benefits apply to all of the products the agency regulates,

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 30 of 93 this initiative was especially focused on products that in recent years have been the subject of important misrepresentation.

As part of the December 18 announcement, FDA released the "Dietary Supplement Enforcement Report" that pledged to closely scrutinize and bring enforcement actions against products identified as "clearly problematic." Dietary supplements that falsely claim effectiveness as treatments for overweight were included among those identified as "clearly problematic."

CFSAN and the Office of Regulatory Affairs have focused their dietary supplement enforcement budgets principally on targeted inspections and, where appropriate, recommending enforcement action against parties who violate the Dietary Supplement Health and Education Act (DSHEA). In terms of the strategies used to enforce DSHEA, FDA has proceeded on several fronts: (1) traditional enforcement activities (e.g., inspections, warning letters, seizures and injunctions, criminal enforcement); (2) inter-agency and international enforcement; and (3) consumer and industry education.

More recently, in December 2003, FTC staff released a report, *Deception in Weight-loss Advertising Workshop: Seizing Opportunities and Building partnerships to Stop Weight-Loss Fraud* (FTC, 2003). This FTC staff report lays out a number of opportunities for industry and media to assume a leadership role in addressing deceptive weight loss advertising. To complement these efforts, the OWG recommends that FDA continue its enforcement initiative targeted at misleading claims about dietary supplement weight loss products.

C. Therapeutics

Therapeutics Recommendation Highlights:

- Convene an FDA advisory committee meeting to address challenges, as well as gaps in knowledge, about existing drug therapies for the treatment of obesity.
- Continue discussions with pharmaceutical and medical device sponsors about development of new obesity therapies.
- Revise 1996 draft guidance on developing obesity drugs and re-issue for comment.

The Commissioner directed the OWG to "develop an approach for facilitating the development of therapeutics for the treatment of obesity."

The role of obesity in many acute and chronic diseases is well documented. The contribution of obesity to premature mortality through increased risks of diabetes, heart disease, stroke, and cancer, among others, mandates an aggressive, proactive stance by the entire medical community.

1. Background

Modern medicine's experience with weight loss drugs dates to the late nineteenth century when initial enthusiasm for the weight loss properties of thyroid extract were eventually tempered by the negative effects that iatrogenic hyperthyroidism had on lean muscle mass, bone, the central nervous system (CNS), and cardiac

FDA/CFSAN - Calories Count: Report of the Working Group on Obesity

function (Schwartz, 1986; Bray, 1976). The next century of obesity drug development saw the introduction of a number of drugs that proved to have significant side effects: Dinitrophenol (cataracts, neuropathy) in 1934; Amphetamine (addiction, CNS and cardiac toxicity) in 1937; Rainbow pills, or digitalis and diuretics (cardiac arrest) in 1967; Aminorex (pulmonary hypertension) in 1971; and Redux (cardiac valvulopathy) in 1996 (Bray and Greenway, 1999).

Prior to 1996, all approved obesity drugs were labeled for short-term treatment of obesity based on pre-approval clinical trials of up to 12 weeks' duration and of limited size by today's standards. Over the past 10-15 years, increasing recognition of several facts have led to changes in the approach to the treatment of obesity and thus to the study of new drugs for this condition: (1) obesity is a chronic condition with long-term morbid and mortal sequelae; (2) maintenance of weight loss, even while on continued drug therapy (and certainly after discontinuation of drugs) is the rare exception rather than the rule; and (3) maintenance of a "healthy" weight (rather than weight "cycling") is the key to reduced risk for obesity-associated adverse sequelae.

2. FDA's Draft Guidance

In 1996, FDA issued draft guidance entitled "Guidance for the Clinical Evaluation of Weight-Control Drugs." The draft guidance gives recommendations for the design and conduct of phase 1-3 clinical studies aimed at demonstrating the effectiveness and safety of weight-loss medications. (21) This guidance proposed two alternative criteria for effectiveness for drug therapies:

- Mean weight loss in the drug-treated group is 5% greater than the mean weight loss in the placebo group following one year of treatment.
- The proportion of patients that lose at least 5% of their baseline weight is greater in the drug vs. the placebo group.

3. Existing Therapies

Under the criteria in the 1996 draft guidance, three drugs have been approved for the long-term treatment of obesity: dexfenfluramine (Redux) in 1996 (withdrawn in 1997 for safety reasons), sibutramine (Meridia) in 1997, and orlistat (Xenical) in 1999. In addition, a number of drugs were approved prior to 1996 for the short-term (e.g., a few weeks) treatment of obesity (e.g., phentermine (Adipex) and diethylpropion (Tenuate)).

FDA-approved drugs for the long and short-term treatment of obesity are indicated for use by those patients with: (1) a body mass index of $> 27 \text{ kg/m}^2$ when accompanied by obesity-related comorbidities such as hypertension, diabetes, and dyslipidmeia; or (2) a body mass index $> 30 \text{ kg/m}^2$.

For patients with extreme obesity (those with BMIs at or over 40), for whom no other measures have been effective in promoting weight loss, surgical or device-mediated gastroplasty is increasingly employed. Worldwide, over 100,000 of these devices have been implanted over the past 8 years. In the United States alone, tens of thousands of devices are implanted each year to restrict the size of the stomach and thus severely limit food intake. Despite serious complications, gastroplasty procedures as well as device implantations are effective for some individuals, with average durable loss of 35-40% of excess (over ideal) weight.

4. OWG Therapeutics Recommendations

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 32 of 93 Ideally, individual consumers will avoid becoming overweight or obese through diet and exercise. Yet the OWG recognizes that obese and extremely obese individuals are likely to need medical intervention to reduce weight and mitigate associated diseases and other adverse health effects. The OWG concurs with agency plans to (1) convene an FDA advisory committee meeting to address challenges, as well as gaps in knowledge, about existing therapies (i.e., head-to-head comparisons of marketed drugs, cardiovascular endpoint studies); (2) continue discussion with pharmaceutical and medical device sponsors about new obesity medical products; and (3) revise 1996 draft guidance on developing obesity drugs and re-issue for comment.

D. Research

Research Recommendation Highlights:

- Pursue research on obesity prevention with USDA/ARS.
- Support and collaborate, as appropriate, on obesity-related research with others, including NIH
- Pursue obesity related research in the following five areas:
 - Information used to facilitate consumers' weight management decisions.
 - o Relationship between overweight/obesity and food patterns.
 - o Incentives to product reformulation
 - Potential for FDA regulated products unintentionally to contribute to or result in obesity
 - Translational research conducted by the National Center for Toxicological Research (NCTR) and CFSAN's Office of Applied Research and Safety Assessment (OARSA)

The Commissioner directed the OWG to "identify applied and basic research needs relative to obesity that include the development of healthier foods as well as a better understanding of consumer behavior and motivation."

1. Joint Research with USDA/ARS

As part of its research efforts, the OWG recommends that FDA collaborate with USDA/ARS on a national obesity prevention conference to be held in October 2004. The conference will draw on the expertise of both the public and private sector scientific communities to provide guidance for research agendas in the short- and long-term to address obesity prevention from a variety of scientific and other disciplines. Such disciplines will include diet and nutrition, behavioral and economic science, and research involving exercise, education, integrated programs, and outreach.

2. Survey of Research

The OWG focused on three areas of research related to its charge: (1) "labeling information" and consumer perceptions and dietary behaviors with regard to weight management; and (2) support for safety evaluation with

respect to the potential for FDA regulated products unintentionally to contribute to or result in obesity; and (3) translational research conducted by FDA's National Center for Toxicological Research and CFSAN's Office of Applied Research and Safety Assessment. to enable the agency to use the basic scientific research conducted by such agencies as the NIH in FDA's regulatory activities. Of these three, the OWG considers the first two to be more directly and immediately relevant to its charge. Translational research, because of its link to basic nature, takes a long time to yield practical results. Nevertheless, the OWG believes FDA should continue to conduct translational research in order to gain a better understanding of obesity.

Based on a review of the relevant research as well as comments provided during a variety of public meetings, the OWG has identified several knowledge gaps related to the two research areas above. The OWG recommends that further obesity-related research be conducted in the following areas: (1) information used to facilitate consumers' weight management decisions, (2) the relationship between overweight/obesity and food consumption patterns, (3) incentives to product reformulation, and (4) the potential for FDA-regulated products unintentionally to contribute to or result in obesity, and (5) the extension of basic research findings to the regulatory environment through translational research. In addition, the OWG recommends that FDA pursue collaborations with other groups who are undertaking obesity research such as NIH, which has recently issued an obesity research agenda, and CDC.

Information used to facilitate consumers' weight management decisions. The OWG recommends conducting additional qualitative and quantitative research with an emphasis on (1) consumer reaction to and effectiveness of current packaged food labeling and possible changes to the food label (e.g., highlighting calories, listing the quantitative amounts for all nutrients in multi-size packages, and using "healthy" symbols, graphic devices, or caloric/nutrient density indicators), (2) consumer reaction to and effectiveness of current restaurant nutrition information and possible changes (e.g., listing nutritional information such as calories, fat and sodium for both *a la carte* items and meals and using "healthy" symbols), and (3) consumer dietary behavior and attitudes toward weight management.

Relationship between obesity and food consumption patterns. The OWG recommends conducting research to evaluate the relationship between obesity in adults and children and the frequency of foods obtained from and/or consumed in different locations (e.g., home cooked meals, packaged foods, and quickservice establishments/ restaurants) and with respect to socioeconomic status and vulnerable populations (e.g., Hispanic Americans, African Americans, American Indians, and the elderly). This research would be conducted in collaboration with the Economic Research Service of the USDA using CDC and National Health and Nutrition Education Survey data to evaluate these relationships.

Incentives to product reformulation. The OWG recommends conducting further research with the packaged food and restaurant industries in addition to that currently being conducted by OASPE in collaboration with FDA (FDA, 2003). This research would (1) examine whether the incentives (e.g., label prominence and other label characteristics of calorie and weight management information) and barriers (e.g., food additive and claims approval processes and the regulatory policy related to standards of identity and fortification) to reformulation identified by the packaged food industry during previous discussions are real or perceived, and (2) expand the scope of the research conducted by OASPE to include additional discussions with key restaurant industry, including quickservice, personnel regarding the barriers and incentives to the development/reformulation of healthier restaurant foods.

Potential for FDA-regulated products to unintentionally contribute to or result in obesity. Although most FDA-regulated products are intended to be used or consumed for purposes other than weight management, weight

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 34 of 93 gain may be an unintentional adverse side effect associated with use of some of these products. In general, for both foods and drugs, weight gain or obesity has not consistently been measured, evaluated, or considered as an adverse effect when designing study protocols or evaluating submitted research results. Strategies to systematically evaluate this endpoint are needed as part of the safety assessment for FDA-regulated foods and drugs. Thus, the OWG recommends conducting research to investigate (1) the promotion of weight gain as an adverse side effect of FDA-regulated drugs and whether this is a factor that should be taken into account regarding drug safety and (2) the development of animal model assessment strategies that encompass the evaluation of long-term effects on weight gain as a safety assessment parameter.

Translational research. Translational research is essential for FDA to use basic research from other agencies and academic institutions in developing regulatory policies and actions. Thus, the OWG recommends extending basic research on (1) developmental imprinting (23) to differentiate among food components and eating behaviors of neonates, or nutrient/food component exposures of fetuses via maternal diets, with regard to weight management challenges in adolescence and adulthood, (2) biomarker and effects-evaluation techniques through emerging genomics, proteomics and metabolomics technologies to identify how FDA-regulated products modify risk factors and susceptibilities for weight gain, obesity, and co-morbidities, and (3) development of animal models to evaluate the effects of diets and dietary components, drug therapies, and medical device uses on long-term weight maintenance, health and longevity. The OWG further recommends that FDA take into account translational as well as other obesity-related research being done by NIH, as it considers future research in these areas.

VI. Stakeholder Investment to Help Ensure Results

Stakeholder Investment Recommendation Highlight:

• Continue to promote and engage in active dialogue with invested stakeholders.

The Commissioner charged the OWG to set out specific means for developing and implementing "an active dialogue with outside invested stakeholders including consumers groups, academia, and the food and restaurant industry on developing a framework for consumers to receive messages about reducing obesity and achieving better nutrition."

A. Background

Recognizing the high level of interest in obesity among FDA's many stakeholders, the OWG initiated a process for establishing ongoing relationships with individuals and organizations from all sectors. A key aspect of this process included providing the public with multiple opportunities to become involved in a dialogue with the OWG on its activities and the issues associated with helping consumers address the problem of obesity.

As one of its first major outreach initiatives, the OWG sponsored a public meeting on October 23, 2003, (24) to accomplish several objectives:

• To initiate a discussion of FDA's role and responsibilities in addressing the major public health problem

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 35 of 93 of obesity;

- To focus on issues related to promoting better consumer dietary and lifestyle choices that have the potential to significantly improve the health and well-being of Americans; and
- To obtain stakeholder views on how best to build a framework for messages to consumers about reducing obesity and achieving better nutrition.

Approximately 320 attendees representing diverse stakeholder viewpoints registered to participate in this discussion, with nineteen organizations making formal presentations on issues associated with the six focus questions. These nineteen organizations represented science/research, academia, consumers, health and medical associations, industry, and advocacy groups. In addition to the formal presentations given at the October 23 public meeting, interested and concerned stakeholders submitted written comments to Docket No. 2003N-0338 on various aspects of the six focus questions.

The scope of the discussion at this meeting, and at two subsequent roundtable meetings (held with health professionals/academicians and with consumer groups, on December 15-16, 2003, respectively) centered on the following six focus questions:

1. What is the available evidence on the effectiveness of various education campaigns to reduce obesity?

Stakeholders regarded education as an essential component of FDA's contribution to public health efforts to confront the problem of obesity. Stakeholders consistently reinforced FDA's leadership role in educating the public about the food label, good nutrition, and healthy diets.

Stakeholder comments focused on four key areas: (a) effectiveness of existing education campaigns; (b) type of education campaigns needed; (c) what campaigns should address; and (d) what messages are likely to affect weight gain, weight management, or weight loss.

2. What are the top priorities for nutrition research to reduce obesity in children?

Stakeholders were particularly concerned about childhood obesity. Stakeholders emphasized the importance of parental involvement in efforts to address childhood obesity. The views focused on the scope of the problem, as well as on the research on activities that are needed to address the issue of childhood obesity.

3. What is the available evidence that FDA can look to in order to guide rational, effective public efforts to prevent and treat obesity by behavioral or medical interventions, or combinations or both?

Stakeholders expressed a range of views and perspectives about what would inform FDA decisions in preventing and treating obesity.

4. Are there changes needed to food labeling that could result in the development of healthier, lower calorie foods by industry and the selection of healthier, lower calorie foods by consumers?

Stakeholders were highly interested in participating in the area of food labeling. The views focused on (a) general advice; (b) calories; (c) energy balance; (d) serving sizes; (e) current health-related information on the

FDA/CFSAN - Calories Count: Report of the Working Group on Obesity

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 36 of 93 label; (f) consumer education on the food label; (g) messages on the food label; and (h) expanding nutrition information availability in restaurants.

5. What opportunities exist for the development of healthier foods/diets and what research might best support the development of healthier foods?

Stakeholders provided a diverse array of research needs, creative incentives for the development of healthier foods/diets, and general advice.

6. Based on the scientific evidence available today, what are the most important things that FDA could do that would make a significant difference in efforts to address the problem of overweight and obesity?

Stakeholder views related to three major categories: (a) food labels; (b) research; and (c) education.

On November 20, 2003, FDA, in conjunction with OASPE, sponsored a workshop on "Exploring the Connections Between Weight Management and Food Labels and Packaging." The two major issues explored at this workshop were:

- Current food labels and packaging: Effects on weight management and reduced risk of overweight and obesity and
- Data supporting options for change

This daylong workshop involved presentations by researchers, academicians, and public health officials, who discussed issues such as the effect of portion/package size, shape and structure on consumption (e.g., comments by Brian Wansink in transcript of November 20 workshop); and presentations by representatives of the restaurant industry, who addressed issues surrounding provision of nutrition information in restaurants.

The OWG organized the comments to Docket No. 2003N-0338 into a searchable database that informed preparation of this report.

FDA also met with representatives of the packaged food and restaurant industries to learn about their obesity-related activities.

B. OWG Stakeholder Investment Recommendations

The OWG believes it is worthwhile to maintain contacts with stakeholders concerned about the obesity issue both to benefit from their continued involvement and to ensure that, to the extent possible, collective obesity efforts are mutually supportive.

VII. Overall Conclusions

In response to the charge to the OWG, this report provides a range of recommendations for addressing the obesity epidemic. These recommendations address multiple facets of the obesity problem under FDA's purview, including developing appropriate and effective consumer messages to aid consumers in making wiser dietary

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 37 of 93 choices; formulating educational strategies in the form of partnerships, to support the dissemination and understanding of these messages; specific new initiatives to improve the labeling of packaged foods with respect to caloric and other nutritional information; initiatives enlisting and involving restaurants in the effort to combat obesity; the development of new therapeutics; the design and conduct of effective research in the fight against obesity; and the continuing involvement of stakeholders in the process.

As noted previously in this report, achieving ultimate success against obesity will occur only as a result of the complementary efforts over time by many concerned sectors of our society. It is the belief and the hope of the OWG that the recommendations contained in this report, when carried out by FDA in concert with the complementary ongoing and planned efforts of other sister DHHS agencies and other agencies of government, will make a significant impact in reversing current trends.

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Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 39 of 93

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Notes:

(2) National Institutes of Health (NIH) clinical guidelines (http://www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/risk.htm#limitations) define "overweight" in adults as a body mass index (BMI) of 25.0 to 29.9, and "obesity" as a BMI of 30.0 or higher. BMI (see Text Box at Appendix B) is defined as the ratio of a person's bodyweight in kilograms divided by the square of his or her height in meters.

(3) For additional information on factors contributing to obesity see CDC webpage (http://www.cdc.gov/nccdphp/dnpa/obesity/contributing_factors.htm)

(4) In children, the BMI is expressed as percentile growth that is based on gender-and age specific growth charts.

- (5) When the OWG was formed, Joseph A. Levitt was the Director of CFSAN, and the OWG vice-chair. As of January 5, 2004, Dr. Brackett became director of CFSAN, and assumed the role of vice-chair.
- ⁽⁶⁾ For a further discussion of energy balance see, *Dietary Reference Intakes* Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids Part 2, Chapter 12 Physical Activity; 12:1-39 (Institute of Medicine of the National Academies, 2002) and references cited therein.
- (7) Although alcoholic beverages are not a focus of this report, there is some interest in having calorie and other nutrition information declared on the label of such beverages, as evidenced by a recent petition from the Center for Science in the Public Interest (CSPI) submitted to the Tax and Trade Bureau of the Treasury Department. In a letter dated December 17, 2003, to DHHS Secretary Thompson, CSPI requested that DHHS support the petition.
- (8) As noted earlier in Section II.A.1., there is much discussion in the field of nutrition concerning the specific macronutrient source of calories, but given the charge to focus on obesity, the OWG believes that a primary focus on calories is appropriate.
- (9) For more information on *Steps to a HealthierUS* see http://www.healthierus.gov/steps/index.html
- (10) For more information on the *HealthierUS* Initiative see http://www.healthierus.gov/
- (11) In addition, the focus groups explored what type of nutrition information they would like to see in quickservice restaurants (see section V.B.1.of this report). Participants discussed and reacted to various presentations of nutrition information at restaurants.
- (12) IFIC states that its mission is to communicate science-based information on food safety and nutrition to health and nutrition professionals, educators, journalists, government officials and others providing information to consumers. IFIC states that its purpose is to bridge the gap between science and communications by collecting and disseminating scientific information on food safety, nutrition and health and by working with an extensive roster of scientific experts and through partnerships to help translate research into understandable and useful information for opinion leaders and ultimately, consumers. IFIC is supported primarily by the food, beverage and agricultural industries.
- (13) The %DV indicates the amount of a nutrient present in a serving in relation to reference levels for a daily diet. The reference levels for vitamins and minerals are based on Recommended Dietary Allowances established by the National Academies; the reference levels for macronutrients are based on recommendations in the *Dietary Guidelines for Americans* or as established by public health organizations. For macronutrients whose recommended intake levels are based on caloric intake (e.g., saturated fat intake should be less than 10% of calories), the %DV is calculated for a 2,000 calorie diet.
- (14) USDA's Healthy Eating Index is a summary measure of overall diet quality. It provides a picture of the type and quantity of foods people eat and the degree to which diets comply with specific recommendations in the *Dietary Guidelines for Americans* and USDA's Food Guide Pyramid. For further information go to http://www.

usda.gov/cnpp/healthyeating.html

- (15) The Food Labeling Compliance Program gives instructions to FDA Field Offices that describes food labeling enforcement strategies and identifies/highlights specific areas where resources should be targeted with regard to the accuracy of the food label.(currently on the Internet at: http://www.cfsan.fda.gov/~comm/cp21008.html)
- (16) For a further discussion on carbohydrates, see *Dietary Reference Intakes* Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids Part 1, Chapter 6 Dietary Carbohydrates: Sugars and Starches 6:1-57 (Institute of Medicine of the National Academies, 2002) and references cited therein.
- (17) Guidelines for Use of Nutrition Claims (CAC/GL 23-1997).
- (18) Guide to Food Labeling and Advertising. Section VI. Nutrient Content Claims 6.1.9(c).
- (19) This example also contains an express nutrient content claim ("try our delicious low fat yogurt"), and two relative claims ("29 percent fewer calories" and "86 percent less fat"). Hence, the statement, as written, would need to meet the regulatory requirements for these types of claims, and would also need to provide serving size information that would allow for appropriate comparison between the cherry pie and the cherry yogurt.
- (20) From remarks by Hudson Riehle of the National Restaurant Association at the November 20, 2003, workshop "Exploring the Connections Between Weight Management and Food Labels and Packaging" (http://www.fda.gov/ohrms/dockets/03n0338/03n0338-tr.htm)
- On January 26, 2004 (69 FR 3588), FDA issued a *Federal Register* notice specifically to solicit comments on this previously published draft guidance. FDA is interested in incorporating the latest scientific advances in the field of obesity and drug development into an amended obesity guidance document. Once the agency revises the draft, FDA will issue the guidance again for comment before finalizing the guidance.
- (22) For the purposes of V.D.2., "labeling information" includes possible changes to the NFP, possible changes to the PDP, graphic devices, caloric/nutrient density indicators, and nutrient content claims.
- (23) The developmental imprinting hypothesis suggests that the increase in childhood obesity is, in part, a result of an epigenetic effect of poor nutrition or exposure to some toxic agent during the perinatal period when metabolic pathways are being established in the fetus and neonate, creating a dysfunctional metabolic pathway. As the child ages, these dysfunctional metabolic pathways, in conjunction with other factors, such as inadequate exercise, may become sufficient to cause or contribute to overweight or obesity. This developmental programming hypothesis, developed from epidemiological data, has also been recently extended to animal models.
- (24) In the *Federal Register* of October 8, 2003 (68 FR 58117), FDA announced this public meeting. Transcript of the meeting is available in FDA Docket No. 2003N-0338, and as of the date of this report, available on the Internet at (http://www.fda.gov/ohrms/dockets/dockets/03n0338/03n0338-tr.htm).

Case 1:08-cv-01000-RJH Document 33-6

t 33-6 Filed 02/15/2008

Page 43 of 93

(25) In the *Federal Register* of October 17, 2003 (68 FR 59795), FDA announced this public workshop. On November 19, 2003 (68 FR 65303), FDA amended its original announcement to reflect that the agency was requesting comments regarding the workshop. Transcript of the workshop is available in FDA Docket No. 2003N-0338, and as of the date of this report, available on the Internet at (http://www.fda.gov/ohrms/dockets/dockets/03n0338/03n0338-tr.htm)

(26) This listing includes references in the Report and Appendices B and H

Food Labeling and Nutrition | Calories Count

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March 12, 2004

Counting Calories Report of the Working Group on Obesity

Appendix A List of Acronyms and Abbreviations

Table of Contents

ANPRM Advance notice of proposed rulemaking

BMI Body mass index

CDC Centers for Disease Control and Prevention

CFSAN Center for Food Safety and Applied Nutrition

CNS Central nervous system

CSFII USDA 1994-1996 Continuing Survey of Food Intakes by Individuals

CSPI Center for Science in the Public Interest

DSHEA Dietary Supplement and Health Education Act of 1994

DHHS U.S. Department of Health and Human Services

FDA Food and Drug Administration

FTC Federal Trade Commission

FR Federal Register

IFIC International Food Information Council

IOM Institute of Medicine

NFP Nutrition facts panel

NIH National Institutes of Health

FDA/CFSAN - Report of the Working Group on Obesity: Appendix A - List of Acronyms and Abbreviations

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 45 of 93

NLEA Nutrition Labeling and Education Act of 1990

OASPE DHHS Office of the Assistant Secretary for Planning and Evaluation

OWG FDA's Obesity Working Group

PDP Principal display panel

RACCs Reference amounts customarily consumed

the Act Federal Food, Drug, and Cosmetic Act

USDA U.S. Department of Agriculture

USDA/ARS U.S. Department of Agriculture/Agricultural Research Service

%DV Percent Daily Value

21 CFR Title 21, Code of Federal Regulations

Food Labeling and Nutrition | Calories Count

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March 12, 2004

Counting Calories Report of the Working Group on Obesity

Appendix B Text Boxes on Body Mass Index (BMI), Energy (Calorie) Balance, Carbohydrates and Other Macronutrient Contributions to Caloric Value

Table of Contents

Body Mass Index (BMI)

Body mass index (BMI) is a way of characterizing weight status. For example, an adult's weight status is classified as underweight (BMI < 18.5), normal (BMI = 18.5 - 24.9), overweight (BMI = 25.0 - 29.9), or obese (BMI = 30.0). For children and adolescents, somewhat different BMI ranges are used to classify their weight status. The BMI has gained increasing use by health professionals because it is highly correlated with body fat.

The BMI values used to classify adults as underweight, normal, overweight, or obese are based on their ability to predict the effect of body weight on the risk for some diseases. For example, common conditions associated with increased risk in adults classified as being overweight or obese include premature death, cardiovascular disease, high blood pressure, osteoarthritis, some cancers, and diabetes. Although BMI is only one of many factors used to predict the risk of these diseases, it is an important factor and one that can be modified by individual changes in eating and physical activity behaviors.

For adults, BMIs are calculated from mathematical formulas that take into account an individual's height and weight. BMI can be calculated using pounds

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 47 of 93 and inches with this equation:

BMI = (weight in pounds/(height in inches x height in inches) x 703

A calculator that automatically estimates the BMI for an individual is available on the CDC Web page (http://www.cdc.gov/nccdphp/dnpa/bmi/calc-bmi.htm).

BMI values for children and teens are used to assess their body fatness changes over the years as they grow. Unlike adults, where the same BMI ranges are used for both men and women and across all ages, gender- and age-specific BMI values are used to classify the weight status of children and teens. This is necessary because children's body fat levels change over the years as they grow. Also, girls and boys differ in their body fat levels as they mature. BMI decreases during the preschool years and subsequently increases into adulthood. BMI-forage tools are useful for children and teens because they compare well to laboratory measures of body fat levels and can be used to track body size throughout life. More information on BMI values for children is available on the CDC Web page (http://www.cdc.gov/nccdphp/dnpa/bmi/bmi-for-age.htm).

For some individuals such as athletes who have a muscular body with relatively small amounts of body fat, the use of BMI values may inappropriately classify them as overweight. For these individuals, the additional use of other estimates of body fat such as waist circumference may help to more accurately estimate their weight status. For example, a waist measurement greater than 40 inches in men and 35 inches in women is usually indicative of excessive abdominal fat, which is an independent predictor of risk factors and ailments associated with obesity.

Calorie (Energy) Balance⁽¹⁾

Overweight and obesity result from an imbalance that occurs when the calories consumed exceeds the calories expended. Even small imbalances over time can result in weight changes. For example, a difference of one 12-oz soda (approximately 150 calories) or 30 minutes of brisk walking most days can add or subtract approximately 10 pounds of body weight per year.

There are many physiological factors (e.g., gut hormones) that operate to maintain body weight at a constant level even though calorie intake often varies considerably from day to day and week to week. (2) The physiological factors regulating food intake tend to be more effective in defending against weight loss than against weight gain. This is thought to be an adaptive mechanism that protected humans from the adverse effects of famine and starvation. However, the physiological factors that tend to maintain calorie balance can be

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 48 of 93 overwhelmed by environmental and behavioral factors that favor high calorie consumption or low physical activity. When weight gain occurs, a person's energy balance thermostat is reset to achieve calorie balance at the new, higher level of body weight. Thus once weight gain occurs, a new calorie balance level is established. The body then tends to defend against weight loss from this new, larger weight status.

Although the tendency for overweight and obesity is a product of complex interactions between physiological, genetic, environmental, and behavioral factors, the rapid increase in rates of overweight and obesity in the United States over the last several decades has occurred too rapidly for changes in genetic or physiological mechanisms to be solely the cause. Therefore, the emerging obesity epidemic is almost certainly due to changes in consumer food choices and physical activity levels resulting in an overall positive calorie balance and weight gain.

Total calorie intake refers to all energy consumed as food and drink. Proteins, carbohydrates, fat, and alcohol provide 4, 4, 9, and 7 calories per gram, respectively. Some calories (e.g., approximately 1.5 calories per gram) are obtained from dietary fiber that undergoes bacterial degradation in the large intestine to produce volatile fatty acids which are then absorbed and used as energy in the body. Physical activity such as walking 2 miles in 30 minutes burns approximately 150 calories. Because of limited capacity to convert excess calories to protein or carbohydrate, the body stores excess calories as body fat, regardless of whether the excess calories are caused by inadequate physical activity or excessive intakes of calories from any of the nutrient sources of calories. Reductions in large body fat reserves, which have often accumulated gradually over long periods of time, and subsequent maintenance of healthy body weight, will likely require long-term commitments to changes in eating and physical activity.

⁽¹⁾ The term "energy balance" is commonly used to describe the relationship between the number of calories consumed from foods and the calories used by the body. For purposes of this document, however, the term "calorie balance" is used in place of "energy balance" since calories are the unit of energy measurement used for nutrition labeling and best understood by consumers. Therefore, in this document, the terms "energy balance" and "caloric balance" are used interchangeably.

⁽²⁾ Among the factors affecting body weight are body size and fat-free mass (i.e., the weight of the body less the weight of its fat mass) and also to a lesser degree age, gender, body composition, nutritional status, inherited variations, and/or differences in the hormonal status. Physical activity is the most variable of the calorie expenditures among individuals. For some individuals, physical activity is only a small proportion of the total calorie requirements; for very active

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 49 of 93 individuals, it can be a significant proportion of daily calorie needs. Body weight is a major determinant of the calorie expenditure from physical activity. For example, the calorie cost of walking a mile at a moderate pace is 69 calories for a 140 pound individual and 58 calories for a person weighing 114 pounds. The intensity of physical activity can also affect calorie expenditure. For example, more calories are expended when jogging than when walking for the same amount of time.

Carbohydrates and Other Macronutrient Contributions to Caloric Value

Macronutrients are the components of food that provide energy (i.e., calories). There are three categories of macronutrients: carbohydrates, proteins and fats. Carbohydrates represent over half, and fats about a third, of the energy intake of typical Western diets. Understanding the caloric contribution of macronutrients to the diet requires knowledge of their chemical composition.

Carbohydrates - Carbohydrates (sugars, e.g., glucose, sucrose; and starches) provide energy to cells in the body and glucose is a primary source of energy for the brain. Sugars and starches are broken down to glucose and the energy provided is 4 calories per gram. Other types of carbohydrates such as sugar alcohols (e.g., sorbitol, maltitol) and dietary fiber are not well absorbed by the small intestine and are fermented by bacteria in the large intestine. Carbohydrates that are fermented in this manner provide a lower energy value per gram.

The rapidity and extent of carbohydrate absorption by the body directly influence the speed and extent of the rise in blood glucose (i.e., glycemic response), which, in turn, triggers an insulin response. The glycemic index of carbohydrate-containing foods has been proposed as a way to quantify the blood glucose response following their consumption (Jenkins et al., 1981). Many factors can affect the glycemic index of a single food, especially when the food is consumed in a meal.

Foods or meals that have a high glycemic index trigger the release of insulin into the blood. Elevated blood insulin levels stimulate the uptake of fat from the blood into fat cells, and inhibit the breakdown and release of stored fat from fat cells. Some scientists believe that consuming a high glycemic index food (e.g., a food that contains sugar or starch) can result in an increase in stored body fat.

Weight loss plans based on greatly restricting carbohydrate intakes have been promoted for more than a decade. "Low" carbohydrate products are being promoted as a way to reduce weight and to assist diabetics in their control of

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 50 of 93 carbohydrate intake; however, not all carbohydrates raise blood glucose levels, nor deliver the same energy value per gram. In addition, when one macronutrient is restricted in a food product, it is often replaced with another macronutrient. For example, when "low" fat products were introduced several years ago, carbohydrates often were the replacement macronutrient. In many of the current "low" carbohydrate products marketed today, fat is often the replacement macronutrient. Also today many of the low carbohydrate products replace the high glycemic index carbohydrates (e.g., sugars and starches) with other carbohydrates such as sugar alcohols, which have no measurable glycemic index and may provide fewer calories per gram. Thus, it is important to look at the NFP to determine the calorie content of and the type of carbohydrate in a product. (1)

Fats (lipids) - A major source of energy for the body is derived from fats (lipids). Fats aid in the absorption of fat-soluble vitamins and carotenoids. There are two essential fatty acids, a-linolenic and linoleic. Fats contribute 9 calories per gram. There are three major components: saturated fatty acids, trans fatty acids and unsaturated fatty acids (monounsaturated fatty acids and polyunsaturated fatty acids). All yield the same caloric value, but may affect metabolism differently. Saturated fatty acids and trans fatty acids raise blood lipid levels, especially cholesterol and low density lipoprotein cholesterol, which have known adverse health effects. There is no known requirement for trans fatty acid for specific body functions.

Acceptable Macronutrient Distribution Range (AMDR) has been estimated for individuals. The AMDR is the range of intake for a particular energy source that is associated with reduced risk of chronic disease while providing adequate intakes of essential nutrients. The AMDR for carbohydrates and fats is estimated to be 45 to 65 and 20 to 35 percent of energy, respectively, for all adults. Consumption of carbohydrates and fats within these ranges reduces the risk for obesity, as well as certain chronic diseases such as coronary heart disease and diabetes.

Proteins - Proteins make up the major structural components of cells and are composed of amino acids. There are 20 essential amino acids. Proteins function as enzymes, hormones, and have other important functions in the body. Proteins provide 4 calories per gram. Animal protein sources (e.g., meat, milk, eggs) generally contain balanced amounts of the essential amino acids whereas vegetable protein sources frequently have a limited amount of one of the essential amino acids. Foods that are low in fat tend also to be low in protein; foods that are low in carbohydrate tend to be high in protein and fat.

⁽¹⁾ FDA has received petitions requesting that the agency provide for nutrient content claims related to the carbohydrate content of foods. As discussed in section V.A.3.b., the OWG recommends that FDA file these petitions and

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 51 of 93 publish a proposed rule to provide for nutrient content claims related to the carbohydrate content of foods, including guidance for the use of the term "net" in relation to carbohydrate content of foods.

Food Labeling and Nutrition | Calories Count

<u>CFSAN Home | CFSAN Search/Subject Index | CFSAN Disclaimers & Privacy Policy | CFSAN Accessibility/Help FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA </u>

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U.S. Food and Drug Administration



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FDA Home Page | CFSAN Home | Search/Subject Index | Q & A | Help

March 12, 2004

Counting Calories Report of the Working Group on Obesity

Appendix C Notice Concerning July 30, 2003 Secretary's Roundtable on Obesity/Nutrition

Table of Contents

July 30, 2003

Department of Health and Human Services Secretary's Roundtable on Obesity/Nutrition Wednesday, July 30, 2003 10:00 a.m. - 12:00 noon Washington, D.C.

Public Docket 2003N-0338

The Department of Health and Human Services (HHS) has established a public docket 2003N-0338 to receive additional information, perspectives, and suggestions from participants who attended the Secretary's Roundtable on Obesity/Nutrition on July 30, 2003.

Obesity is a growing and urgent public health problem in the United States. To address this problem, HHS Secretary Tommy G. Thompson has led the Department in its efforts to encourage healthy habits such as healthy diets, more exercise, and making healthy choices. Secretary Thompson continues to challenge HHS agencies and the leadership of the public health community to intensify their efforts to realize these improvements. The Secretary's Roundtable on Obesity/Nutrition is intended to enhance an HHS discussion with leading thinkers and experts in the public health community on the role that HHS can play in reducing or reversing the weight gain that leads to obesity. The Roundtable agenda included the following five focus questions:

- 1. What is the available evidence on the effectiveness of various education campaigns to reduce obesity?
- 2. What are the top priorities for nutrition research to reduce obesity in children?

- 3. What is the available evidence supporting whether public efforts should prioritize behavioral interventions to prevent obesity versus medical interventions to treat obesity?
- 4. What changes to food labeling could result in the development of healthier, lower calorie foods and the selection of healthier, lower calorie foods by consumers? What opportunities exist for the development of healthier foods/diets and what research might best support the development of healthier foods?
- 5. Based on the scientific foundation available today, what is the one thing that HHS could do that would make a significant difference in efforts to address the problem of obesity?

The Department has opened public docket 2003N-0338 to receive additional information, references, or thoughts from Roundtable participants in follow up to the July 30 discussion. We would appreciate receiving all follow up information and views by *Tuesday*, *September 30*, 2003. You should submit written comments to the Dockets Management Branch (FDA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. You may also submit comments electronically to http://www.fda.gov/dockets/ecomments or by email to FDADOCKETS@oc.fda.gov We request that you submit two copies of any written comments; individuals may submit one copy. Please ensure that you include the docket number 2003N-0338 in your submission. All comments submitted to the public docket are public information and may be posted to the FDA website (http://www.fda.gov) for public viewing.

Food Labeling and Nutrition | Calories Count

<u>CFSAN Home | CFSAN Search/Subject Index | CFSAN Disclaimers & Privacy Policy | CFSAN Accessibility/Help</u>
<u>FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA</u>

FDA/Center for Food Safety & Applied Nutrition Hypertext updated by <u>las/ear</u> March 12, 2004



U.S. Food and Drug Administration



CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FDA Home Page | CFSAN Home | Search/Subject Index | Q & A | Help

March 12, 2004

Counting Calories Report of the Working Group on Obesity

Appendix D August 11, 2003, Charge Memorandum

Table of Contents

Food and Drug Administration Rockville MD 20857

FROM: Commissioner of Food and

Drugs

TO: Lester M. Crawford, DVM, Ph.

D.

Deputy Commissioner

Food and Drug Administration

DATE: August 11, 2003

SUBJECT: FDA Obesity Working Group

I am requesting the formation of a Working Group to confront the current obesity epidemic in the United States and to develop new and innovative ways to help consumers lead healthier lives through better nutrition. This issue is a top priority of the Office of the Commissioner as well as of the public health community both within and outside of government, because of the importance of consumer choices in preventing the serious health consequences associated with obesity, and in improving the health of the population. I am requesting that you serve as the Chair of this Working Group. Because the leadership role on nutrition issues in FDA resides within the Center for Food Safety and Applied Nutrition (CFSAN), I am requesting that Joseph Levitt, Director of CFSAN, assist you as the Vice Chair of this Working Group.

The goal of the FDA Obesity Working Group is to issue, within six months, a report that includes an action plan setting out specific means for developing and implementing the following goals:

- 1. Message.
 - The Working Group will develop a clear, coherent, and effective FDA message (within the broader context of DHHS) that will unify various public and private efforts to reverse the current obesity epidemic.

Page 55 of 93

- 2. Education Program to Deliver the Message.
 - o Outline an FDA program (component of DHHS program) for educating Americans about obesity and the means to prevent the disease.
- 3. Supporting the Message.
 - o *Food Labels:* Develop an approach for enhancing and improving the food label to assist consumers in preventing weight gain and reducing obesity;
 - o *Restaurants:* Develop an approach for working with the restaurant industry to create an environment conducive to better informed consumers;
 - o *Therapeutic Treatment:* Develop an approach for facilitating the development of therapeutics for the treatment of obesity;
 - Research: Identify applied and basic research needs relative to obesity that include the
 development of healthier foods as well as a better understanding of consumer behavior and
 motivation.
- 4. Stakeholder Investment to Ensure Results.
 - Provide for an active dialogue with outside invested stakeholders including consumer groups, academia, and the food and restaurant industry on developing a framework for consumers to receive messages about reducing obesity and achieving better nutrition.

Please consult with Joe Levitt as soon as possible regarding those who should be called upon to serve on the Working Group either as members or as supporting staff. While I encourage you to include experts from across FDA's Centers, as well as the Office of the Commissioner, I expect the Working Group's activities to be focused in and led by CFSAN. I also encourage you to seek the advice and input of other HHS agencies as needed.

Please report back to me by September 12, 2003, regarding the membership of the Working Group and an overall timetable for the group's work.

Thank you in advance for assuming a leadership role in confronting this extremely important and challenging public health crisis.

Mark B. McClellan, M.D.; Ph.D.



U.S. Food and Drug Administration



CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FDA Home Page | CFSAN Home | Search/Subject Index | Q & A | Help

March 12, 2004

Counting Calories Report of the Working Group on Obesity

Appendix E FDA Obesity Working Group

Table of Contents

MEMBERS

Name	Title / Affiliation
Lester Crawford (Chair)	Deputy Commissioner/Food and Drug Administration (FDA)
Robert Brackett (Vice Chair) ⁽²⁷⁾	Director/Center for Food Safety and Applied Nutrition (CFSAN)
Pat Kuntze (Executive Assistant)	Sr. Advisor for Consumer Affairs/ FDA
Peter Salsbury (Executive Secretariat)	Acting Director, Executive Operations Staff/CFSAN
Alan Rulis	Senior Advisor for Applied Nutrition/ CFSAN
Susan Bond	Special Assistant to the Deputy Commissioner/FDA
Donna Howard	Special Assistant to the Senior Advisor for Applied Nutrition/ CFSAN
Anne Crawford	Assistant to the Senior Advisor for Applied Nutrition/CFSAN

FDA/CFSAN - Report of the Working Group on Obesity: Appendix E - FDA Obesity Working Group

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 57 of 93

Director, Office of Nutritional

Christine Taylor Products, Labeling, and Dietary

Supplements (ONPLDS)/CFSAN

Elizabeth Yetley Lead Scientist for Nutrition/CFSAN

Kathy Ellwood Director, Div. of Nutrition Programs

and Labeling, ONPLDS/CFSAN

Director, Div. of Market Studies,

Richard Williams Office of Scientific Analysis and

Support (OSAS)/CFSAN

David Acheson Chief Medical Officer/CFSAN

Director, Division of Metabolic and

David Orloff

Endocrinologic Drugs/Center for Drug Evaluation and Research

(CDER)

Peter Pitts Associate Commissioner for

External Relations/FDA

Mike Landa

Deputy General Counsel, Office of

the Chief Counsel/FDA

Tomas Philipson

Senior Economic Advisor to the

Commissioner/FDA

ADJUNCT MEMBERS (support workgroup as needed)

Name Title / Affiliation

Virginia Wilkening Deputy Director/ONPLDS/CFSAN

Steven Bradbard Supervisory Psychologist, Division of Market Studies,

OSAS/CFSAN

Lisa Lubin

Consumer Safety Officer, Office of Food Additive

Safety (OFAS)/CFSAN

Rick Canady

Senior Science Policy Analyst, Office of Science

Coordination and Communication (OSCC)/FDA

Jeff Shuren Assistant Commissioner for Policy, Office of Policy,

Planning, and Legislation (OPPL)/FDA

Susan Bernard Senior Public Health Advisor, OPPL/OC

Susan Wood Director, Office of Women's Health, OSCC/OC

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 58 of 93

Joanne Lupton Visiting Scholar, CFSAN

EXTERNAL LIAISONS

Name	Title / Affiliation
Van Hubbard	Director, National Institutes of Health (NIH) Division of Nutrition Research Coordination
Karen Donato	Coordinator, NIH National Heart, Lung, and Blood Institute Obesity Education Initiative
William Dietz	Director, Division of Nutrition and Physical Activity/ Centers for Disease Control and Prevention (CDC)
Judith McDivitt	Team Leader for Health Communications, Division of Nutrition and Physical Activity/CDC
Karyl Thomas Rattay	Physical Activity, Nutrition and Children's Health Advisor, Office of Disease Prevention and Health Promotion/U.S. Department of Health and Human Services (DHHS)
Jonelle C. Rowe	Senior Medical Advisor, Office of Women s Health/ DHHS

(27)When the OWG was formed, Joseph A. Levitt was the Director of CFSAN, and the OWG vice-chair. As of January 5, 2004, Dr. Brackett became director of CFSAN, and assumed the role of vice-chair.

Food Labeling and Nutrition | Calories Count

<u>CFSAN Home</u> | <u>CFSAN Search/Subject Index</u> | <u>CFSAN Disclaimers & Privacy Policy</u> | <u>CFSAN Accessibility/Help</u>
<u>FDA Home Page</u> | <u>Search FDA Site</u> | <u>FDA A-Z Index</u> | <u>Contact FDA</u>

FDA/Center for Food Safety & Applied Nutrition Hypertext updated by <u>las/ear</u> March 12, 2004



U.S. Food and Drug Administration



CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FDA Home Page | CFSAN Home | Search/Subject Index | Q & A | Help

March 12, 2004

Counting Calories Report of the Working Group on Obesity

Appendix F FDA Obesity Working Group Subgroup Members

Table of Contents

OBESITY KNOWLEDGE BASE

Lead: Donna Howard

Members: Rick Canady, Elizabeth Yetley, Rich Williams, Kathy Koehler, Theresa Mullin, Susan Bernard,

Anne Crawford, Brian Somers

MESSAGE

Lead (Message): Peter Pitts

Members: Christine Taylor, Naomi Kulakow, Steven Bradbard, Vicky Kao, Susan Bernard, Nancy Ostrove

EDUCATION

Lead (Education): Susan Bond

Members: Marjorie Davidson, Naomi Kulakow, Steven Bradbard, Jeannie Ertter-Prego, Susan Wood,

Kimberly Rawlings, Susan Bernard, Vicky Kao

FOOD LABELS

Lead: Kathy Ellwood

Members: Virginia Wilkening, Felicia Satchell, Amy Lando, Alan Levy, Mary Brandt, Lori LeGault, Ritu

Nalubola

Document 33-6

Filed 02/15/2008

Page 60 of 93

RESTAURANTS/INDUSTRY

Co-Leads: Tomas Philipson and Susan Bond

Members: Mike Landa, Faye Feldstein, Glenda Lewis, Rich Williams, Clark Nardinelli, Carolyn Young,

Andrew Estrin, Mark Schwartz

THERAPEUTICS

Lead: David Orloff

Members: Eric Colman, Patricia Beaston

RESEARCH

Lead: David Acheson

Members: William Slikker, Kathy Ellwood, Rick Canady, Elizabeth Yetley, Lisa Lubin, Virginia Wilkening,

Richard Williams, Jeremiah Fasano, Shirley Blakely, Eileen Parish, Kathleen Koehler

STAKEHOLDER INVESTMENT

Lead: Pat Kuntze

Members: Lisa Lubin, Brian Somers, Jonathan Chappell, Juanita Yates, Amber Jessup, Ray Formanek, Jennie

Butler, Darlease Hyman, Mary Hitch, Alyson Saben, Patricia Alexander, Alta Hayes, John Henkel, Susan

Cruzan, Jane Peterson

REPORT WRITING

Lead: Alan Rulis

Members: Mike Landa, Paulette Gaynor, Pete Salsbury, Anne Crawford, Brian Somers, Virginia Wilkening,

Cindy Wise

Food Labeling and Nutrition | Calories Count

<u>CFSAN Home</u> | <u>CFSAN Search/Subject Index</u> | <u>CFSAN Disclaimers & Privacy Policy</u> | <u>CFSAN Accessibility/Help</u> FDA Home Page | Search FDA Site | FDA A-Z Index | Contact FDA

> FDA/Center for Food Safety & Applied Nutrition Hypertext updated by las/ear/cjm March 22, 2004

Case 1:08-cv-01000-RJH

Document 33-6

Filed 02/15/2008

Page 61 of 93



U.S. Food and Drug Administration



CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FDA Home Page | CFSAN Home | Search/Subject Index | Q & A | Help

March 12, 2004

Counting Calories Report of the Working Group on Obesity

Appendix G Report from the Division of Market Studies Office of Scientific Analysis and Support, FDA CFSAN

Table of Contents

Office of Scientific Analysis and Support Center for Food Safety and Applied Nutrition, FDA

In support of the Obesity Working Group, FDA

December 28, 2003

Study Authors:

Richard A. Williams - Director, DMS

Amber Jessup - Project Officer

Amy Lando - Project Officer

Cristina McLaughlin - Project Officer

David J. Zorn - Project Officer

Kathleen M. Koehler - Primary Writer and Editor

Steve Bradbard - Team Leader, Consumer Studies

Clark Nardinelli - Team Leader, Economics

Contributors to Literature Review:

Steve Bradbard, Andrew Estrin, Amber Jessup, Kathleen Koehler, Amy Lando, Jordan Lin, Clark Nardinelli, Linda Verrill, David Zorn, Judy Labiner

* This report was prepared for Ms. Laina Bush of the Office of the Assistant Secretary for Planning and Evaluation, DHHS. Ms. Bush funded the studies and is a Project Officer on all of the individual studies except the survey of restaurant Web sites.

Helping Consumers Lead Healthier Lives through Better Nutrition:
A Social Sciences Approach to Consumer Information, Food Choices and Weight
Management

A Report from the Division of Market Studies
Office of Scientific Analysis and Support, FDA CFSAN

January, 2004

Executive Summary

This summarizes an interim report on the social science research on weight management done for both the Obesity Working Groups in FDA and the Office of the Assistant Secretary for Planning and Evaluation, DHHS. In these studies, we examined how consumers use existing food labels for weight management; how changes to food labels might improve those practices; how restaurants are currently labeling; how consumers would react to different kinds of labels; and what policies could induce manufacturers to produce healthier foods. Our research has included both review of the current social sciences literature and some new studies. First, in qualitative studies, consumers claim they do not wish to spend a significant amount of time reading and comprehending labels. This is borne out by the fact that many use health or nutrient content claims as signals as to the quality of the entire product and do not check the nutrition facts panel on the back. Also, consumers appear to be confused by serving sizes, particularly by multiple servings listed on small packages, as well as by percentage daily values listed in the nutrition facts panel. Consumers use food labels for multiple reasons, including diet plans and pre-existing health conditions such as diabetes and heart disease, and look for macronutrients of concern. Although we found some labeling in restaurants (by examining their websites), consumers clearly want more nutrition information in restaurants although most claim they will use it only part of the time. In fact, the limited number of studies we examined showed mixed results as to whether restaurant labels would be used but studies also show a correlation of overweight with a higher percentage of food consumed away from home. Consumers state qualitatively that they would like all nutrition information in restaurants but would even find calorie labeling helpful. Finally, consumers appear to be interested in signals of healthy foods, both in supermarkets and restaurants. In interviews, manufacturers state that to encourage production of healthier foods FDA should examine not just labeling policies, but other areas that affect product formulations such as food standards.

Two projects underway are not far enough along to give interim reports. The first is the creation of an economic model of food choice that will answer such questions as, "do food labels help consumers maintain their desired weight"? In addition, we are in the process of getting a restaurant chain to investigate actual market consumer reactions to nutrition labeling on menu boards. The source of our suggested menu board changes will be the results of our focus group studies. Beyond these initial studies, additional research could be done for food labels to investigate both whole package labeling (instead of serving sizes) and nutrient density labeling (e.g., calories per cup). To give consumers better signals, we could also investigate the use of a logo on the front of the package to both signal consumers to the presence of a healthy (or healthier) food and to serve as a motivator for production of such foods. Alternatively, we could evaluate the effectiveness of educating consumers on both the use of daily values and how servings sizes should be evaluated in light of portion sizes. The relationship between eating out and weight management could be investigated both for various kinds of restaurants and for different socioeconomic groups. Finally, there are a number of existing FDA policies such as food standards and nutrient content claims that could be examined to see how changes could encourage more reformulation toward lower calorie or healthy foods.

I. Purpose

In August, 2003, FDA Commissioner Mark B. McClellan declared FDA's intention to confront the current obesity epidemic in the United States and to develop new and innovative ways to help consumers lead healthier lives through better nutrition. FDA's Center for Food Safety and Applied Nutrition (CFSAN) plays a leadership role in nutrition issues at FDA. Within CFSAN, the Division of Market Studies (DMS) in the Office of Scientific Analysis and Support (OSAS) provides expertise in Social and Population Science issues related to CFSAN's mission, including expertise in Economics and Consumer Sciences. Our first charge was to undertake a group of short-term studies on: a) how consumers use current food labels to maintain weight; b) how consumers would use potential changes in food labels, including new labeling in restaurants; and, c) how manufacturers react to labeling requirements with new products and product reformulation. Our second charge was to develop a longer term research agenda on labeling and weight management.

The research goal is to develop knowledge on how to lower the cost (time and effort in choosing foods) to consumers of managing their weight, using labeling and education. In choosing foods for healthy eating, consumers must solve a series of information problems including: 1) determining what constitutes a healthy diet; 2) finding products that meet their nutritional needs; and, 3) evaluating nutritional characteristics of particular products. This information comes from a variety of sources such as media, friends, school, physicians and, of course, food labels and restaurant menus. From the standpoint of consumer behavior, or the "demand side" of the market, we will examine the psychology of people's perceptions, eating habits and desires relative to healthy eating and weight management. From the standpoint of producer behavior, or the "supply side" of the market, we examine how producers make decisions to make and market healthy foods (including decisions about serving and package sizes) and provide information about those foods. Our research follows the natural division of packaged food products in grocery stores and food consumed in restaurants, although issues in these two areas often overlap. Our results are cross-cutting, with relevance to several areas, including food labels, restaurants and research.

II. General Concepts of Weight Management

Public health importance. The scope of the growing and urgent public health problem of obesity was outlined in the Surgeon General's Report (US DHHS 2001). In 1999-2000, 65% of U.S. adults were overweight, increased from 56% when surveyed in 1988-1994; 30% of adults were obese, increased from 23% in the earlier survey (Flegal 2002). Among children age 6 through 19 years, 15% were overweight, compared with 10 to 11% in the earlier survey (Ogden 2002). Overweight and obesity are associated with increased morbidity and mortality. It is estimated that about 300,000 deaths per year may be attributed to obesity, and overweight and obesity increase the risk for coronary heart disease, type 2 diabetes, and certain cancers (Allison 1999, US DHHS 2001). The total economic cost of obesity in the United States is about \$100 billion per year, including more than \$50 billion in avoidable medical costs, more than 5 percent of total annual health care expenditures (**US DHHS 2001, Finkelstein 2003).**

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 63 of 93

Energy balance. Weight gain occurs when there is an energy imbalance, with "energy in" (calories from food) exceeding "energy out" (resting metabolism plus physical activity). This report addresses issues related to the "energy in" side of the energy balance equation: food choices and the food environment. A general consideration of increasing "energy out" through physical activity, while important, is beyond the scope of this report. However, we do consider how information about the physical activity equivalent of food calories might affect consumer food choices.

Genes and the environment. Genetic influences on obesity are complex and are just beginning to be elucidated (Shuldiner 2003). Based on twin, adoption and family studies, it is estimated that 40 to 70% of the current population variation in body mass index (BMI) can be explained by genetic factors (Shuldiner 2003, Allison 2003). However, even relatively modest decreases in the remaining, non-genetic, "environmental liability" for obesity can nevertheless be predicted to result in meaningful decreases in BMI and corresponding health risks (Allison 2003).

Weight management and the food environment. Evidence from research on taste preferences, eating regulation and weight-loss interventions suggests that overweight individuals and those prone to overweight may be particularly vulnerable to the modern food environment (Lowe 2003). This "obesigenic" environment features unlimited quantities of a variety of foods high in caloric density (which tend to be foods high in fat, sugar, or both), together with minimal need for energy expenditure (Lowe 2003), perhaps making it more difficult for obesity prone individuals to regulate energy intake. A promising approach to improving weight control is therefore to focus on changes in the food environment: the availability, structure, composition and portion size of foods. There is potential for changes in the food environment both at the general (or population) level and at the level of the individual (personal food environment). For example, a change in the food environment at the population level might be the availability of more food choices that facilitate weight control. A change in the personal food environment might be to stock one's home with ingredients and foods that facilitate weight control (Lowe, 2003). A current challenge is to provide information and assistance to enhance the ability to determine one's personal food environment.

The role of food labeling. Since passage of the Nutrition Labeling and Education Act 10 years ago, consumers have had nutrition labeling on most packaged foods (small product lines were excluded as were foods packaged on premises in supermarkets and delis). As discussed later, it is clear that consumers both like and use the nutrition information on the back of food packages and the health and nutrient content claims on the front of packages. However, it is not clear how successful consumers have been at using labels to eat healthy diets. Research is necessary to establish whether the food label is as useful as it could be in assisting consumers by making weight management as easy as possible.

The role of restaurants. Unless restaurants make nutrient content or health claims, they are not required to provide consumers with any information on the nutrient content of their foods, an obvious gap in information. This exclusion applies to all eating places away from home, including school cafeterias, nursing homes, military establishments and hospitals. Research is needed on how to address the current information gap by tailoring labeling to the special circumstances of eating places away from home. Unlike packaged food, restaurant food is characterized by frequent recipe changes, both for routine use and at the request of consumers for special preparation. This may have been an insurmountable hurdle for most restaurants in the past, when nutrition information had to be determined by direct chemical analysis. However, this hurdle may be decreased at present with the ubiquitous availability of nutrient composition databases and software for labeling, coupled with the explosive growth in personal computers and personal digital assistants, even if the restaurant labeling lacks the precision of that now required of packaged foods.

A changing environment. In the quantum uncertainty principle in physics, observation of a system perturbs the system, resulting in measurement uncertainty. Similarly with the restaurant industry, recent attention by public health officials, litigators and the media on restaurants and weight management issues has resulted in changes in the marketplace. Restaurants have begun offering more nutrition information and featuring healthier menu selections. Research is needed to describe current restaurant practices, and to evaluate their effectiveness in assisting consumers with weight management. Additionally, although the introduction of healthier food selections by packaged food manufacturers dates to before the passage of NLEA, the current interest in weight management is likely to speed the introduction of products for healthier eating.

III. Overview of Current Issues and Related Literature

A. Current Issues.

In response to current concern about problems of obesity and weight management, some specific issues have emerged in articles, statements, presentations, and dialogue among consumers, industry, scientists and public health officials.

Consumers and packaged food labels. Even though food labels are widely used and accepted in the population, there are potential problems that may be limiting food label use or its effectiveness as a tool in weight management.

- Numerical calories. Is the numerical calorie designation prominent enough on the food label? Do consumers understand and use the numerical calorie designation? Do consumers do the math needed to calculate their daily caloric intake using food labels? Should they do so? Can or should consumers know how their own recommended calorie intake compares with the 2000 calorie per day reference on the food label?
- Daily Values. Do consumers understand or use the percent Daily Value (%DV) figures on food labels? If they neither use nor understand them, can consumer education develop an appreciation and understanding of these figures? How can the food label best help consumers place the calorie content of foods in the context of a daily diet: for example, add a %DV for calories, add a qualifier such as "high",

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 64 of 93 "medium", "low", use symbols to indicate "high", "medium", "low", etc?

- Serving sizes. Larger package sizes that are commonly consumed in one sitting may contain two or more standard servings for nutrition labeling. If consumers are not aware of the number of serving sizes, they may believe they are consuming fewer calories than they are if they consume the entire package.
- **Nutrition goals**. Because consumers are interested in different types of nutrition information from food labels depending on their particular health concern or diet, do they want to know, in a global sense, whether or not a food is "healthy"? Would consumers benefit from qualitative symbols or cues on labels of "healthy" foods?
- **Trade-offs**. Rather than numerically calculate a "daily diet", consumers may rather try to choose foods that are healthy when they are inclined. They may balance a healthy choice if they have made an unhealthy choice in the previous eating occasion, but not quantitatively. How can the food label use qualitative symbols or cues to build on consumers' inclinations for qualitative "trade-offs"?
- "Halo" effects of claims. A "halo" effect occurs when a consumer reacts to a particular positive claim about a product and assumes that the entire product has positive attributes. For example, a low fat claim may signal to some consumers that the product is also low calorie. How can the food label use claims effectively to assist consumers in weight management, while avoiding halo effects or other unintended consequences of claims?

Restaurants. As noted above, the absence of calorie and nutrition labeling of restaurant food represents an information gap.

- Portion size and calories. In part because of large portion sizes in many restaurant offerings, the calorie content of restaurant meals may be much higher than consumers realize. Additionally, restaurant offerings may have higher calorie and saturated fat density (per weight or volume) than similar foods eaten at home. Would better availability of calorie information in restaurants help consumers with weight management?
- **Restaurant information format.** Some restaurants voluntarily offer nutrition information, but it is often not in an accessible format. The information is often available only after purchase, and may have confusing charts or formats and very small type size. What is the current status of voluntary restaurant nutrition information and what guidelines for format and availability would best help the consumer with weight management?
- **Menu item variability.** Are there creative approaches that would make restaurant nutrition labeling feasible in spite of the variations in menu item preparation?

Food Formulation. Changes in food labels and shifts in consumer perceptions and public health concerns can change the incentives and constraints food manufacturers face in producing and marketing foods. Producers may decide to change the formulation of foods if their expected private benefits exceed their expected private costs. Reformulation of existing products or introduction of new products occurred as a result of the appearance of health claims on food packages in the 1980's, the mandatory listing of fat content on food labels in the 1990's and awareness and proposed labeling of trans fat in the late 1990's.

• Weight management and food reformulation. Have producers formulated products to be low in calories or to respond to the weight management issue? What are the barriers or incentives to food formulation for weight management? How could these barriers be removed or incentives provided?

B. Related Literature.

[Contributors to literature review: Steve Bradbard, Andrew Estrin, Amber Jessup, Kathleen Koehler, Amy Lando, Jordan Lin, Clark Nardinelli, Linda Verrill, David Zorn]

The importance of social science principles in formulating and implementing nutrition policy was recognized years ago with the work of the National Research Council's Committee on Food Habits during World War Two (Gifford 2002). More recently, FDA conducted consumer research before the implementation of NLEA, to determine the usefulness of potential choices for the Facts panel format. Since NLEA, FDA and other researchers have studied how consumers use the Nutrition Facts panel, nutrient content claims, and health claims (separately and in combination) to make dietary choices.

Consumer research is used to assess people's knowledge, attitudes, perceptions, and preferences for a topical subject area or reactions to any type of stimuli. Research methods may include qualitative studies, such as focus groups; quantitative, nationally representative surveys, using structured questionnaires; experimental studies of consumer responses to labeling and package variations; and intervention studies of the effects of point of purchase labeling.

Food label use and diet. Research clearly shows that most Americans are familiar with and use the Nutrition Facts panel. In a 2002 FDA survey, 69 percent of the U.S. population reported using food labels often or sometimes when they buy a product for the first time (FDA, 2003). Our more detailed review of the literature on food label use is in Appendix A. The literature on food label use was also recently reviewed by the Institute of Medicine (IOM 2003).

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 65 of 93 In FDA's survey, people reported using the food label for many reasons, most commonly to see how high or low the food is in calories and in nutrients such as fat, sodium, or certain vitamins (FDA 2003). However, although consumers report using the food label to make dietary choices, they may not fully understand all of the information on the Nutrition Facts panel, particularly the %DV (Appendix A, IOM 2003). Evidence from experimental studies suggests that %DV information can help consumers judge the healthfulness of a food better than absolute amounts of nutrients alone (Levy, Fein, and Schucker, 1996 and Barone et al, 1996). However, in some surveys the majority of respondents could not accurately define or use the %DV for fat (FMI 1996, Levy et al 2000).

In experimental studies, consumers could correctly use the Nutrition Facts panel on the back of food packages to verify and evaluate the health and nutrient content claims on the front of packages (Garretson and Burton, Mitra et al, Ford et al., Roe et al.). However, when there was no Nutrition Facts panel, consumers were misled by claims into thinking a product was -healthier than it really was (Ford et al., Roe et al.) and when consumers were not specifically directed to consult the Nutrition Facts panel some cut short their information search and drew conclusions based on health or nutrient content claims (on the front of the package) alone (Roe, Levy and Derby).

As noted by the Institute of Medicine, the body of literature on the association of food label use and diet is relatively small (IOM 2003) Several studies have reported correlations between food label use and diet (Appendix A). For example, survey respondents who used the Nutrition Facts panel were more likely to consume a lower fat diet, both in the general population and among family clinic patients (Neuhouser et al, Kreuter et al). Clinic patients with health conditions such as high blood pressure and high cholesterol were more likely to look on the label for sodium and cholesterol information, respectively (Kreuter et al).

The calorie content of food is a common use of the food label, and was among the top three pieces of information sought by 80 percent of label readers in one survey (IOM 2003). However, there has been little research on the relationship between label use and weight management/weight loss or gain.

The use of "healthy" food logos on food packages was recently reviewed (Smith et al 2002). Such programs feature a package logo or symbol on food meeting certain nutrition criteria set by the program's administering body. Examples include the U.S. American Heart Association "Heart Check", the Canadian Heart and Stroke Foundation "Health Check", the Australian "Pick the Tick" and the Swedish "Green Keyhole". In general, consumers report support for the programs and are able to interpret meaning accurately (Smith et al 2002). Some evidence also indicates the programs have a positive effect on food formulation. Additional research is needed on the effect of such programs on food purchase and consumption (Smith et al 2002).

Restaurants. A number of experimental studies have examined consumer behavior in cafeteria, restaurant and vending machine settings in response to nutrition information or health messages. The results of these studies are mixed; differences in results among studies may be due to differences in experimental designs, including size of sample, demographic characteristics of participants, experimental setting, length of study, type of nutrition information or health message and type of behavioral outcome studied (Appendix A).

In general, consumers have mixed reactions to nutrition information in cafeterias and restaurants. Both health claims and listing of nutrition information have been found to be capable of producing positive influences on consumer evaluations of menu items and the influences appear to be strongest when nutrition information about alternative menu items is absent. Although nutrition information may influence choices and attitudes, other factors may be more salient: whether the respondent is on a diet, attitudes toward nutrition, price of food, health claim vs. nutrition information, taste/perceived taste.

An analysis of studies received from the USDA Economic Research Service (their own and others) shows that eating away from home, particularly increasing consumption in fast food restaurants, is correlated with increases in BMI. Further, the per capita number of restaurants in a state was positively related to individual's BMI and the probability of being overweight. See Appendix A for charts summarizing these studies, used courtesy of USDA ERS.

Motivation. The process of consumers' motivation and readiness for lifestyle changes such as weight management are described by a behavioral sciences model, the Transtheoretical Model of Change (Prochaska). The model identifies five stages-of-change - Pre-contemplation, Contemplation, Preparation, Action, and Maintenance; and emphasizes that a message must be matched to a respective stage in order to be most effective (e.g., messages targeting consumers in the action stage will likely be ineffective for consumers in the pre-contemplation stage). Thus, the effectiveness of food and restaurant labeling or messages for weight management would depend in part on consumer readiness and stage of change.

Portion sizes and energy density. Although consumer motivation is important for weight management, there is also interest in other factors that facilitate weight management in the current "obesigenic" environment. Two aspects of the food environment have been recently highlighted as having implications for weight control: increased portion size and the energy-density of foods. Portion size of restaurant foods increased from the 1970's through the 1990's (Rolls 2003). National survey data show that portion sizes of food eaten both in the home and away from home increased from 1977 to 1998 (Rolls 2003). Energy density refers to the number of calories per given weight or volume of food. The fat content of food increases the energy density and the water content lowers the energy density. Although energy density can be decreased by decreasing the fat content of the food, this approach can be self-limiting because decreasing the fat content also decreases satiety, the extent to which the food satisfies the urge to eat. Research has shown that increasing the proportion of water-rich vegetables in mixed dishes such as casseroles decreases the energy density without decreasing satiety (Rolls 2003).

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 66 of 93

Eating cues. Other research has examined consumer behavior in the context of the eating environment. Results indicated that people's eating responses are often automatic and respond to cues such as package size, shape and structure (Wansink 2003). For example, research participants ate more food when they were given larger containers, even when the food was unpalatable stale popcorn. People also reduced consumption automatically in response to cues such as package structure or dividers, for example, red potato chips at intervals in a tube of regular chips (Wansink). This research suggests that changes in food packaging and presentation can be complementary to labeling and nutrition information in assisting consumers with weight management.

Weight management and economic theory

One economic rationale for government action is a situation called market failure, in which there is a consumer demand not being met by the market. One possible market failure is the absence of nutrition labeling in restaurants, where restaurateurs know more about the nutritional content of their meals than their clients. Further, information remedies provided by the government work best if information is structured in a way that best assists consumer understanding and use. It is not clear after ten years of experience whether the label on packaged food, including both claims and the nutrition facts panel, is presented in the optimal way for consumers.

However, although many consumers clearly wish to lose weight, survey's show that they believe this is primarily the responsibility of each individual. It is not clear exactly which market can help consumers to control their own eating habits although weight loss and diet information and programs and clubs are widely available at reasonable prices. Although there is no obvious market failure, there is a sense that FDA could do more to assist consumers with the important public health issue of weight management. The theory of constitutional economics holds that people often turn to government to constrain their choices to assist them in their long-term goals (Brennan and Buchanan, 1985, especially pp. 67-81), and this theory can provide a rationale for government action on weight management. Consumers may prefer to have food choices externally constrained rather than to bear the cost of restraining their own food consumption. If FDA can take actions that alter the set of food choices offered to consumers, consumers may be better off even if those changes eliminate foods that are currently consumed. An example is stimulating reformulation of current foods through changes in labeling. If labeling causes changes in the food offered to consumers, then the set of available foods has been altered. Consumers may prefer this form of external restraint to voluntarily restraining their daily food consumption.

Changes in product formulation. Evidence suggests that not only do consumers respond to labeling, but producers also respond to consumers' concerns about diet by producing healthier products. Decisions to change the composition of foods will depend on whether producers anticipate that the expected private benefits of changing the formulation will exceed the expected private costs of doing so. Analyses conducted for FDA have examined the effect of hypothetical labeling policy changes on manufacturers' expected decisions to reformulate foods (Honeycutt et al 1998, White et al 2002, Muth et al 2003). Further research is needed with respect to weight management and food formulation; to evaluate how labeling changes might motivate product reformulation, provide opportunities for marketing healthful products, and stimulate competition based on nutrient and health claims that assist consumers with weight management.

III. Current Research Projects.

The Division of market Studies is currently engaged in four short-term projects to address current issues in weight management. The projects are: 1) focus groups on consumer response to nutrition information on packaged food and in restaurants; 2) a survey of nutrition information available on restaurant web sites; 3) discussions with manufacturers regarding incentives and barriers to food formulation; 4) a quantitative social sciences model of dietary and weight management behavior. Preliminary results, currently available for the first three projects, make possible some suggestions for further research and indicate issues for further consideration. We plan to conduct further analysis of the complete results and consideration of the relationships among the four projects.

1. Focus Groups on Food and Restaurant Labeling and Weight Management [Amy Lando, Steve Bradbard]

In response to FDA's concern over the rise in obesity and overweight in the United States, we conducted a series of eight focus groups, funded by HHS/ASPE, to explore: (1) how consumers use the nutrition information on food labels; (2) what type of nutrition information they would like to see in quick service restaurants; and, (3) which messages would be effective as part of a public information and education effort aimed toward encouraging consumers to use the food label. Participants discussed and reacted to variations in the Nutrition Facts Panel and the principal display panel on food packages and to various presentations of nutrition information at restaurants.

The focus groups were held in November and December 2003, in Calverton, Maryland, Philadelphia, San Antonio, Texas, and Chicago. The groups, which each had between 7 to 10 participants, were segregated by gender and education. All focus group participants were at least 18 years old, had been grocery shopping and had eaten in a fast food and/or quick service restaurant in the past month.

TOPLINE RESULTS:

The following findings are preliminary and are based on observations recorded by the observer, as well as post-group discussions with the focus group moderator and other observers. These topline results are not based on a complete analysis of the focus group tapes and/or transcripts, which

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 67 of 93 will be used to compile the Final Report. Also, since these findings are based on qualitative research with small sample sizes, they should not be viewed as nationally representative or projectable.

General Nutrition:

- 1. **Attitudes towards nutrition.** In many of the groups, especially the women's groups, people cared about nutrition and report using the Nutrition Facts Panel (NFP). Many were quite savvy about nutrition. At the same time, however, many also said that they don't always consider nutrition when deciding what to eat. Taste, convenience, price, what kind of mood they are in, and what their family eats were often at odds with healthy eating. While participants were interested in calories, many pointed to multiple concerns that went beyond calories such as the level of saturated fat, total fat, cholesterol, carbohydrates and sodium.
- 2. **Macronutrients.** In general, individual people tended to care more about some macronutrients than others depending on the diet that person was following. In most groups, at least one person was familiar with the Atkins diet and many of these people were most concerned about carbohydrates and sugars. Others were concerned about fat and saturated fat. Some people checked the NFP mostly for information about sodium. Those who were on the Weight Watchers diet were concerned about calories and fiber.
- 3. **% Daily Value.** Very few participants reported using the % Daily Value (%DV) column on the NFP. Either they did not understand the meaning of %DV or they thought that it was not relevant to then since they did not consume a 2000 calorie diet. Those who did use or might use %DV thought that is was a good way estimate how much of a particular nutrient they were eating or to gauge a healthy and balanced diet.

Food Label Modification:

- 4. **Large package sizes.** In all the groups participants were presented with a mock-up of a 20oz soda and large packaged muffin. Both of these products are thought to be commonly consumed in one sitting, but have more than one serving size listed. Most participants said that neither the muffin nor the soda was a healthy food. They pointed out that the soda had a lot of sugar and calories and that the muffin was high in fat, calories, and carbohydrates.
- 5. **Serving versus package.** In general, participants thought it was misleading to list either product as having more than one serving. Many did realize that if you eat the entire package you would need to multiply the serving size by the nutrient of interest, though some were confused and made mistakes when trying to calculate in their heads. They were not surprised to see these products labeled as multiserving packages.
- 6. **Calorie-related variations.** The first test label added a %DV for calories, removed the *calories from fat* line, enlarged the calories line, and changed that way serving size was declared. In general these changes were not noticed by participants. When the new wording for serving size was pointed out, most did not think it was an improvement over the existing language.
- 7. **Serving size variations.** The second test label had two %DV columns on the NFP, one for a single serving and one for the entire package. In the first four groups, the absolute quantities of macronutrients were only listed for the single serving size. After comments from these groups, the label was modified to have the absolute amount for both a serving and the entire product. Participant reaction to this modification was positive, but some thought it was not necessary to list the amount for a single serving, and others preferred to have the absolute amount replace the %DV in the columns.
- 8. **Calorie cues.** We tested both a starburst with the calories per serving (first four groups) and a white square with calories per whole product (last four groups). The starburst was misleading to many since they thought the manufacturer was trying to indicate the entire product had fewer calories than it did. The white square with the total calories per product got mixed reactions, but many just said that they recognized these as high calorie products and would stay away from them.
- 9. "Healthy" (keyhole) symbol. In half of the groups we tested a "healthy" meat lasagna with a purple keyhole symbol on the front of the package. There was generally positive reaction to including a front of package symbol indicating that a product was healthy, as long as they understood the definition of the symbol and could trust that it was true. They believed that they would have to be educated as to the meaning of such a signal. Some mentioned that they would look for the keyhole when they were in a hurry in the store. They expressed some concern that these products would cost more or that they would lack in taste.

Restaurant Labeling:

- 10. **Nutrition information.** Most people seemed interested in having nutrition information available to them when they eat at fast food and/or quick service restaurants, though they might not use it every time they eat out. They suggested that this information could be presented in many locations in the restaurant including food wrappers, tray liners, brochures, on the take-away bags, posters near the counter, and the menu boards.
- 11. **Menu board information.** Participants reacted to multiple versions of a menu board for a typical fast food restaurant. In general, people liked having calories listed after meal items and after combo meals. Those who tend to order *a la carte* preferred to have calories listed after each item, while those who usually order a combo meal preferred to have calories listed for the entire meal. While participants were concerned with multiple macronutrients for foods, having just calories listed was enough for many people. They thought that calories could be a signal for the level of other macronutrients.

- Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 68 of 93

 12. Menu board section. Most participants also reacted favorably to the idea of placing healthier options, including meals, in a separate section of the menu board so they could find healthier options at a quick glance.
- 13. "Healthier" (keyhole) symbol. Many also reacted favorably to the purple keyhole symbol for healthier meals, but some thought that the exact number of calories should be listed as well. Again, the symbol would have to be trusted and consumers would have to understand the meaning of the definition.

Messages:

14. There was no one message that participants universally thought was meaningful or liked. Different groups had different preferences, but many thought some message would be good reminders for them to look at the NFP, and also good for prompting children to examine the label.

In summary, many consumers said they are very interested in nutrition information and they report using the NFP to help them determine what to buy and eat. They are interested in many different nutrients in addition to calories. In all the groups, participants felt that multiserving products that are commonly consumed at one sitting should be labeled as such. Many consumers said they are looking for labels that have uniform and realistic serving sizes and are interested in having nutrition information available to them at fast food restaurants.

Based on this preliminary analysis, these focus groups suggest some questions for future research:

- How many consumers use the %DV and how do they use it? Are there other ways to signal to consumers that a product is high or low in a certain nutrient? Is a healthy symbol on the front panel useful for consumers?
- Are there better ways to communicate serving sizes on the Nutrition Facts Panel?
- How do consumers react to nutrient content claims and health claims about calories on the front panel of packaged foods?
- Will nutrition information on restaurant menu boards or other locations change purchasing behavior?

2. Nutrition Information in Restaurant Menus: An Online Survey [Cristina McLaughlin]

The restaurant industry, especially the chain restaurant industry, has used a variety of methods to inform the public about the nutritional characteristics of menu items, in response to current interest in the contribution of restaurant meals to the American diet. One information source is restaurant company web pages on the Internet. The National Restaurant Association website includes a bulletin highlighting chain restaurant menu offerings or information marketed towards healthy lifestyles (NRA 2003). Each of the 19 restaurant entries includes a short description of the health or nutrition-oriented menu feature, and a link to the specific restaurant web site. A systematic survey of restaurant web sites could provide an overview of available information, and could answer the following questions. What nutritional information is currently available to consumers on the Internet regarding menu items at major chain restaurants? Do restaurant web sites indicate the availability and format of nutrition information found at the restaurant locations? How are chain restaurants responding to current concerns about nutrition and obesity, as indicated by menu features and nutrient profiles on their web sites?

The purpose of this project is to survey restaurant web sites and compile a data base of nutrition information in restaurant menus available in the Internet. The list of restaurants was based on the top 100 United States restaurant firms by sales, obtained by searching Dunn & Bradstreet 2003). The top 100 firms identified in the search own a total of 125 restaurants and chains, including 71 casual dining, 28 fast food and 26 other (upscale, pizza delivery, buffets, etc). We reviewed the websites for each of the 125 restaurants or chains, and summarized the information in an Excel spreadsheet. The next step of the project will be to convert the tabulated information to an Access database.

Sample spreadsheet pages for the first 30 restaurants, ranked by total sales, are included in Appendix C. The spreadsheet provides the restaurant name and description followed by the site page (URL) address that includes the nutrition information or that brings us closest to it. The next columns summarize whether nutrition information is available on the site, and whether the information is interactive or in printable (pdf or html) format; reference to "Light" but no additional nutrition information; indication that nutrition information is available on premises and in what format (menu board, menu, tray liner, napkin, brochure, other); whether the nutrition information covers all menu items or partial or targeted items (such as dietary recommendations); and other information, including features marketed for healthy lifestyles.

Of the 125 restaurant web sites surveyed, 36 included nutrition information as either an interactive tool, such as a meal builder, a printable version or both. Of these, about 22 included printable versions only, 3 were interactive only and 12 provided both. Only 4 restaurant websites made reference to "light" items in their menu without additional nutrition information. The nutrition information, when available online, generally included calories and nutrients covered by nutrition labeling of packaged foods: calories, calories from fat, total fat, saturated fat, sodium, etc. A few websites, such as Wendy's and Au Bon Pain, even included information on trans fat. Although nutrition information was often available online, it was not clear whether similar information would be readily available at the point of purchase. Only a few websites indicated whether the nutrition information available online would be available on premises as well. Further exploration of this question would require actual physical visits to the restaurants.

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 69 of 93

Of the 36 restaurants with nutrition information on their websites, 11 provided both complete nutrition information on all menu items and recommendations for special dietary requirements. Overall, 17 offered nutritional information on their whole menu, and 28 restaurants offered nutrition information on some items such as "Most Popular" or recommended items. Although a number of restaurant web sites provide fairly complete nutrition information online, often the nutrition information was not closely tied to the online menus themselves. Many online menu pages displayed little or no overall emphasis on caloric intake or weight-management-related information. The nutrition information, when provided, was generally in a separate file from the online menu. A few online menus were available in a format that probably resembles the actual, on premises restaurant menu but none of these menus showed information on calories or fat.

In summary, many restaurants, but not a majority, provide some nutrition information on their websites. The nutrition information is often displayed separately from the menu web pages, and of course is also separate from the actual point of purchase of a restaurant meal. Restaurant web sites also provide anecdotal, qualitative information about featured menu items related to nutrition, calories or weight management. Some examples of healthy eating menu features are indicated in the Notes section of our spreadsheets (Appendix C) and summarized in the NRA web page overview (NRA 2003). For future research, we plan to expand our survey to include the top 100 fast food firms, convert the information to a relational (Access) database, and undertake a content analysis or other qualitative review of the restaurant web sites. This qualitative review will more fully describe the current status of restaurant initiatives to assist consumers with weight management.

3. Qualitative Investigation of Motivation for Food Product Reformulation [David Zorn]

Restructuring Consumers' Choices: Changing the Foods Offered to Consumers

Since implementing the NLEA labeling regulations in 1993, FDA has learned the enormous importance to health and nutrition that comes by changing the supply of food. When labeling gave consumers information on certain nutrients that they should consume less of, their net reduction was on average about 1% (Levy et al 1985). Consumers who chose different products reduced consumption by more than 1%, but consumers who did not use the labeled information did not benefit from the labeling of a static product set. But if an existing product is reformulated to reduce its calorie content, then all consumers of that product benefit, even if they are not actively seeking to reduce calories. And new products with fewer calories may attract consumers other than those actively engaged in weight management.

Currently DHHS ASPE and FDA have paid a contractor to conduct confidential discussions with food manufacturers and restaurants to provide input on what FDA could do to encourage them to provide consumers with different food offerings to assist in weight management. Because this research is not yet complete, we are reporting initial findings here (Muth and Kosa, 2003). This preliminary summary provides information on discussions with seven food manufacturers and seven restaurant chains regarding the characteristics of food products and servings. Additional discussions are scheduled in the near future. Once all of the discussions are complete, the contractor will provide a formal report containing a full summary of the discussions and a description of the project background and the methods of the study, including the process for conducting the discussions (Muth and Kosa, 2003)

• Label Prominence

Manufacturers respond to required information depending on how prominent it is required to be on the label. For an earlier project, some manufacturers had indicated that they would only reformulate to reduce trans fat in margarine if information on trans fat was going to be prominently mentioned on the label, either by placing it on a separate line in the Nutrition Facts panel or by allowing nutrition content claims. (Honeycutt, et al., 1998). Currently, the signal on calories is weak relative to other signals on the label. Some manufacturers told us that:

- o the Nutrition Facts panel should focus more on calories and perhaps be simplified.
- o FDA should establish a seal related to weight management goals to give prominence to the issue. Other third party seals are very expensive to use.

Visual Cues

We are learning that consumers use visual cues to judge their food consumption. Changing the packaging of products even with their existing formulations, would likely affect the amount of calories consumed.

o Some manufacturers suggest allowing single serving packages to contain only one serving rather than 2.5 servings; others suggested readjusting labeling serving size to represent the entire package or what people generally eat.

• Dietary and Health Context

It is important that consumers have a context for the information given to them. Currently, the Nutrition Facts panel gives calories only as a scalar number, with no context at all for a complete diet. Some manufacturers suggest

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 70 of 93 giving a daily value for calories, just as there is a daily value for almost every other macronutrient based on a 2000 calorie diet. Case 1:08-cv-01000-RJH

- o development of one message on weight management common to all federal agencies.
- o that consumers be educated about calorie balance, possibly illustrated by pictorials on packages to correspond to energy expenditure activity equivalent to the calorie content of the food.

Reformulation Factors

Four key factors affect how favorable a food category is to being reformulated: cost of reformulation, consumer sensitivity to sensory changes in the product, consumer sensitivity to what is on the product label, and the competitiveness of firms within the food category. A labeling change required by FDA is most likely to result in reformulation when the combination of these factors favors the reformulation, such as for beverages, breakfast foods, dairy products, egg products, infant foods, seafood, soups, and weight control foods (Muth, et al., 2003). It may not be possible to influence reformulation of all foods. However, modest changes in food consumption can result in enormous improvements in public health.

Regulatory Policy

Manufacturers suggested several areas where current regulatory policy is a barrier to reformulation

- o The food additive approval process. One firm even supported user fees to fund a simplified and expedited review process. Improvements in the GRAS notification process have been helpful, but additional steps would encourage innovation. They especially mentioned faster review of artificial sweeteners, including cyclamate. Some manufacturers also recommended that FDA provide stronger advocacy and support for the use of fat and sugar substitutes.
- The claims approval process. Some firms want to be able to make factual nutrient content claims without disqualifying limitations relating to other nutrients, want less wordy claims, and they want the claim approval process expedited. Some manufacturers want to be able to label foods with 80-90 calories as low calorie because below this level it is difficult to provide enough nutrition; some want to be able to use "low carbohydrate" claims.
- o The standards of identity and fortification policy. Allow fortification of reduced calorie products so that they can meet the standards of identity. For example, allow fortification of reduced calorie orange juice with folic acid.
- o Standard calorie values for macronutrients. One manufacturer wanted calories from soluble fiber like oligofructose not to be included in the calorie count at the full 4 calories per gram.

Restaurants and Food Service Establishments

Restaurateurs had the following suggestions.

- Educate consumers about appropriate portion size, caloric balance, eating wisely, and asking for customized orders to reduce calories.
- o Educate consumers that small changes in diet can make significant differences for weight management. Restaurants would disseminate on bags, cups and tray liners.
- o Educate consumers on using restaurant nutrition information that is increasingly available and be flexible on the format and placement of such information.
- Assist restaurants with analytical methods for foods.
- o FDA and FTC need to be more flexible about comparative claims. Currently 20% calorie reductions can't be claimed but they are significant for weight management improvements.

In summary, discussions with manufacturers indicated some areas in which labeling policy and other regulatory policy could provide incentives or remove barriers to manufacturer initiatives to assist consumers with weight management. As noted above, these are preliminary results from the initial manufacturer discussions, which are still in progress. Note that these findings are based on qualitative research with small sample sizes, therefore, they should viewed as suggestive, and not as representative or projectable to all manufacturers. In the near future, we will have information available on a complete analysis of the full set of discussions.

4. Quantitative Social Sciences Model of Dietary and Weight Management Behaviors [Amber Jessup]

Current social sciences literature and data sets contain a wealth of information about consumer decisions affecting weight, including attitudinal and behavioral factors related to exercise, food choice, food quantity, and frequency of eating. Realization of the full potential of this information to address public health questions about obesity will require intensive, systematic review and model-building. FDA, in collaboration with OASPE, is working with a contractor, ERG, to review the literature and build a model focused on food label use and weight management. The main

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 71 of 93 components of the project include: an annotated bibliography and written literature review, theoretical and empirical (data-based) models of label use for weight management and a summary of future research needs.

The model will address important individual and environmental factors that can influence consumer dietary and weight management behaviors. In our review of literature in economics, psychology, nutrition, health behavior, and other social science disciplines we are identifying critical factors affecting motivation and execution, such as habit, risk perception, efficacy of behavior, availability of and access to nutrition and health information, and education. We are organizing information from selected articles in a structured, annotated bibliography with brief summaries of the article focus, economic/econometric model used, data source, statistical methodology, results, including a critical review of strengths and weaknesses, and relation to the modeling project. Examples of the annotated bibliography format are in Appendix B. We will next write a literature review synthesizing the conclusions about label use and weight management that can be drawn from the literature.

The theoretical model will be based on Grossman's theory of a household health production function (Grossman 1972). In this framework, health is produced from a combination of time, purchased goods, and human capital. This approach is appealing because health is typically not a commodity that can be directly purchased, but results from a combination of lifestyle choices and purchases. Under the theory, the consumer maximizes his or her utility from health, leisure, and consumption of other goods, such as food. This model acknowledges that food may enter into consumers' utility function in multiple ways: directly, say, due to the pleasure of eating chocolate cake and indirectly, say, through the detrimental effects of chocolate cake consumption on health. Additionally, the consumer is constrained by both time and income. Information, in the form of labeling, may enter into his or her health production function by affecting the choice of foods and into his or her time constraint by reducing the time required to choose foods.

For building the empirical model, nationally-representative data on food choices, nutrient intakes, and diet and health-related attitudes and knowledge (including nutrition label use) are available from USDA's Continuing Survey of Food Intakes by Individuals (CSFII) and the Diet and Health Knowledge Survey (DHKS), 1989-1991 and 1994- 96. To understand how consumers use labels to aid in managing their weight, we will model caloric intake as predicted by label reading. The independent or predictor variables will include other aspects of health, preferences and attitudes towards food and nutrition and demographic characteristics.

Because of the complex relationships among dietary knowledge and attitudes, label reading, and calorie consumption, there are limitations in the use of cross-sectional data, such as CSFII, to infer causal relationships between label reading and dietary choices. For example, consumers with high levels of knowledge and concern about nutrition are likely to eat a healthier diet than consumers that are unconcerned about nutrition. Consumers who are well informed about nutrition are also more likely to read labels and will be better able to use labels to guide their diet. Conversely, label reading may inform consumers about nutrition. For example, health claims may inform consumers about the relationship between diet and disease, or the presence of a macronutrient on the Nutrition Facts panel may signal to consumers that the macronutrient plays an important role in the diet. Thus, although some studies have using simple, single equation methods such as OLS or probit regressions to describe the relationship between label use and nutrient consumption (Neuhauser et al 1999, Kreuter et al 1997), this approach can establish a correlation between label use and diet, but does not establish a causal relationship.

Studies using more complex techniques, such as a two-stage Heckman selection model or an endogenous switching regression model, have attempted to control for the consumers' self-selection to use labels (Guthrie et al 1995, Kim et al 2000) However, neither of these studies focused on calories, a key dietary variable in weight control, and both studies controlled for self-selection of label reading by using data on nutrition knowledge and attitudes to predict label use. But these characteristics may also be the result of self-selection and therefore may not be suitable controls.

In order to overcome these problems, we will test the robustness of the independent association of label use and caloric intake using several modeling approaches, including a single equation multivariate model, a two-stage model, an endogenous switching regression model, and a model using the difference in label availability between waves of data. The latter approach exploits the implementation of the Nutrition Labeling Education Act (NLEA) in 1994, between waves of the CSFII and DHKS, to conduct a natural experiment of the effect of label changes on consumers. Differences in the effectiveness of label use between waves of the CSFII and DHKS, while controlling for other observable factors, can be reasonably attributed to increased availability and standardization of labels.

This model will enhance understanding of the relationship of dietary behavior and consumer label use and of consumer characteristics that influence the effectiveness of label use. By considering relevant and important individual and environmental factors, this model can go beyond the existing literature to help identify the role that food labels play in health decisions. The model will provide information on the marginal benefits of label use on health and can be used in cost-benefit analysis of current labeling, of possible changes in labeling regulations, and of obesity-related policy issues at FDA and HHS.

We expect to use the model to test the effectiveness of policy interventions such as label changes, product reformulation, and educational messages. The data should also enable us to profile different groups of consumers who have different knowledge, attitude, and behavior; this information can also be useful in identifying and prioritizing intervention and education efforts. For example, the model will attempt to answer questions such as:

- Do food labels help consumers maintain their desired weight?
- Are less educated consumers less able to use food labels to maintain a healthy weight than more educated consumers?

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 72 of 93

• How does ethnicity and other cultural factors affect consumers ability to use the food label?

• How does mother's use of the food label affect the health of their children?

The model developed in this project will use existing data, such as the CSFII/DHKS, BLS price data, and supermarket scanner data. The project will also identify data gaps and recommend additional data collection and improvement of this social sciences model.

IV. Future/Potential research projects for addressing weight management problems

Although not finished, some preliminary observations can be made from our research so far. First, although consumers clearly use food labels, including health claims and the nutrition facts panel, the information may not yet be structured in a way to optimize understanding and use. Second, although our research has uncovered some information being offered in restaurants, consumers appear to want more information and in a more structured format. We have uncovered several promising formats including segregation of meals or logo indicators for low calorie or healthy alternatives. Finally, our research shows that manufacturers will respond to changes in labeling policies to reposition their foods to take advantage of information that is prominently required. These preliminary findings suggest some avenues of future research.

1. Food Labels

Research is needed to find out if there are ways to reformat the nutrition facts panel (NFP) to make it easier to use and to provide incentives for manufacturers to offer more lower calorie foods that are also healthier than the current selection. From the existing literature and from the preliminary reports from the current projects, some possible areas include:

- 1. Daily values either evaluate the effectiveness of an education campaign to see if people will start using these or possibly look for replacements to indicate whether nutrients are high or low. These replacements could be graphical devices or wording changes such as high or low.
- 2. Serving sizes Because consumers are having difficulty, either because of time or ability, with the multiplication necessary to calculate nutrient values consumed, consider replacing some or all nutrient information with total container information or nutrient density information.

Research is also needed to see how we can provide better signals on the front of the label, the principal display panel (PDP). Because consumers often do not look at the back of the label when there is a claim, and often take the claim to apply to the entire product, research is needed to see if FDA can provide an alternative signal that addresses the entire product. This may be an indicator of the healthiness of the product, such as the Swedish keyhole, or an indicator of calories in the product.

2. Restaurants

Research is needed to evaluate the effectiveness of various kinds of nutrition labeling, including labeling calories and indicators of healthiness for both a la carte items and meals. Different kinds of labeling may work differently depending on the type of restaurants, e.g., quick serve versus family style restaurants. The desirability of some type of labeling was conclusive in qualitative research but more quantitative research may be necessary. Also, nutrition labeling in restaurants may not be able to be as precise as labeling for packaged products. It is not clear whether people would use nutrition information in restaurants in a different manner than they would for packaged food. Although there is some information provided to us by the Economic Research Service, it might be useful to more completely establish the link between overweight and the prevalence of eating out, both with respect to the types of restaurants and the socioeconomic characteristics of overweight consumers who eat out frequently It may also be useful to know whether people who perceive themselves to be overweight in fact eat fewer meals in restaurants because of that fact and whether or not, if so, labeling would increase the number of meals eaten out.

Finally, we have a potential volunteer chain of restaurants that will use some of the information obtained from the focus groups to test in an actual market situation how consumers will react to this type of labeling. The final details are expected to be worked out in the next month or two.

3. Food Reformulation

Some of FDA's existing policies for nutrition labeling, food standards and food additives may need to be examined to see if there are barriers to reformulating existing foods. In addition, changes that might be suggested to food labels or restaurant menu's should be evaluated to see how it would change the supply side of the market and increase the number of low calorie/healthy foods or meals offered.

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VII. Appendices

- 1. Review of Literature
- 2. Sample Annotated Bibliography Entries
- 3. Sample Pages from Spreadsheet of Restaurant Web Sites

Appendix A. Review of Literature

Review of literature on nutrition labeling and restaurant point-of-purchase labeling [Contributors to literature review: Amy Lando, Jordan Lin, Andrew Estrin, Amber Jessup, David Zorn, Clark Nardinelli]

Nutrition labeling

The Nutrition Labeling and Education Act (NLEA) (1990) gave FDA authority to require a Nutrition Facts panel on the label of most packaged foods. The Facts panel states the standardized serving size, the number of calories per serving and the amount and percent of the Daily Value (DV) per serving for specified nutrients. (The Daily Value is a reference amount for daily intake of a nutrient in a 2000 calorie diet.) Before NLEA, nutrition labeling was required only in certain instances, such as when claims were made about nutrient content.

In addition to the Nutrition Facts panel, FDA also permits specified nutrient content claims and health claims on food labels. FDA defines criteria for nutrient content claims, such as "low in fat" or "a good source of calcium". Health claims highlight a relationship between a food or nutrient and a disease or health-related condition, such as calcium intake and reduced risk of osteoporosis.

Social science research methods

Before NLEA, FDA conducted consumer research about the usefulness of potential choices for the Facts panel format. Since NLEA, a number of researchers have studied how consumers use the Facts panel, nutrient content claims, and health claims (separately and in combination) to make dietary choices. Consumer research is used to assess people's knowledge, attitudes, perceptions, and preferences for a topical subject area or reactions to any type of stimuli. Depending on the the goals of the project, research methods may include qualitative data collection, quantitative surveys or experimental studies.

- In qualitative research, open-ended questions are used to elicit unstructured consumer reactions and thoughts to different topics or stimuli. Qualitative research, including the focus group format, is useful for obtaining the range of consumer opinions about a given topic and is often conducted as a preliminary step, before quantitative surveys or experimental studies. Unlike experimental studies or quantitative surveys, results from focus groups and other qualitative studies are not generalizable to any population.
- In quantitative surveys, information is collected by structured questionnaires and the resulting data categorized by demographic and other characteristics. When the survey sample is nationally representative, the results provide population estimates and the conclusions can be generalized nationally. Nationally representative surveys can help inform policy makers, risk assessors, and health educators of the knowledge, attitudes and self-reported behavior of the U.S. public about a certain topic.
- Experimental studies test consumer response to manipulated stimuli, such as real or hypothetical food labels that vary in format or content.
 Each respondent is randomly assigned to an experimental group that responds to a particular type of food label. The response of each group is recorded, and differences in response across groups are attributed to the corresponding experimental conditions or labels. Experimental studies can statistically test differences in consumers' understanding of and ability to use different label information and formats.
- Intervention studies are another type of experimental study. Intervention studies measure differences in peoples' behavior when specific

Case 1:08-cy-01000-RJH Document 33-6 Filed 02/15/2008 Page 77 of 93 conditions are varied according to an experimental design. For example, intervention studies may examine purchasing behavior in grocery stores or eating behavior in restaurants in which different types or amounts of nutrition information are presented.

Food label use

Research clearly shows that most Americans are familiar with and use the Nutrition Facts panel. In a 2002 FDA survey, 69 percent of the U.S. population reported using food labels often or sometimes when they buy a product for the first time (FDA, 2003). People reported using the food label for many reasons, most commonly to see how high or low the food is in calories and in nutrients such as fat, sodium, or certain vitamins.

Many consumers do not fully understand the information on the Facts panel, even as they use it to make dietary choices. One study suggest that percent DV information helps consumers judge the healthfulness of a food better than absolute amounts of nutrients alone (Levy, Fein, and Schucker, 1996). However, in a national survey (FMI, 1996) less than half of respondents could accurately identify the meaning of the percent DV for fat and another study found that DVs are not helpful for consumers to make correct judgments about the healthiness of a product (Barone et al, 1996)..

Some experimental food label studies have found that, when presented with nutrient content claims or health claims in the absence of the Nutrition Facts panel, consumers can be misled into thinking a product is healthier than it really is (Ford et al., Roe et al.). These misperceptions may be remedied if consumers also look at the Facts panel. For example, regardless of the fat and fiber claims on the front of packages with varying fat and fiber content, consumers who were asked to read the Facts panel could correctly identify a product as being low or high fat (Garretson and Burton). Varying the level of fiber made no difference in the consumers' perceptions of the healthfulness of the food. This suggests that fat is a more salient nutrient to consumers than is fiber. Similarly, regardless of their education level, consumers presented with the Facts panel could judge product healthfulness correctly even in the presence of an implied claim about heart health ("It Does Your Heart & Good!"). However, without the Facts panel, consumers were significantly more likely to be influenced and potentially misled by health claims (Mitra et al).

In the above studies, the research subjects were specifically directed to consult the Facts panel. However, in a study that gave respondents the option to look at any part of a food package, consumers did not look at the Facts panel to verify claim information, but truncated their examination to just the claim on the front of the package (Roe, Levy and Derby). This resulted in incorrect inferences about the product healthfulness, particularly about nutrients not mentioned on the front. Although more research in this area is needed, this study provides some evidence that consumers do not customarily verify front panel information by consulting the Nutrition Facts panel.

Food label and diet

Correlations between food label use and diet have been reported in a number of studies. For example, survey respondents who used the Facts panel were more likely to consume a lower fat diet, both in the general population and among family clinic patients (Neuhouser et al, Kreuter et al). Clinic patients with health conditions such as high blood pressure and high cholesterol were more likely to look on the label for sodium and cholesterol information, respectively (Kreuter et al).

A limitation in interpreting cross-sectional surveys about label use and diet is that consumers who are concerned about their diet may be more likely to read the nutrition label. Thus, although label reading may be correlated with healthy diet practices, the cause of the healthier diet may be the concern about nutrition, not the label reading. For example, in one study that found lower total fat intake among label users than non-users, consumers with higher fat intakes were less likely to search for fat information on the label and food label use was strongly correlated with attitudes toward food labels (Lin and Lee). In another study using statistical analysis to control for different characteristics of label users and non-users, food label users had lower average percent of calories from total and saturated fat, cholesterol, and sodium than non-label users (Kim, Nayga, and Capps).

In an intervention study using grocery store shelf labels with nutrition information, the nutrition shelf labels increased the purchase of healthier alternatives in some product categories, but decreased the purchase of healthier alternatives in other product categories (Teisl and Levy). The authors suggested that consumers might use an implicit health risk "budget" to compensate for eating healthier foods in some categories where taste differences among choices were small, by eating less healthy foods in categories that had greater taste differences among choices. The ability to make such choices could be beneficial to consumers, although not leading to overall improvements in diet. The results support the idea that providing nutrient information may allow consumers to more easily switch consumption away from "unhealthy" products in those food categories where differences in other quality characteristics are relatively small.

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Restaurant labeling

In 1999, American households spent an average of \$2,116 or 42 percent of their total food expenditure on food away-from-home (BLS 1999). According to the latest data, during 1994-6, away-from-home food, especially from restaurants and fast food locations, contributed 32 percent of daily intakes of energy calories, 32 percent of added sugars, and 37 percent of fat (ERS 2000). Thus, food away-from-home is an important part of American diets and more informed dietary choices away-from-home can potentially help reduce the risk of health problems such as obesity. Nutrition labeling on menus, including the use of claims and symbols, is one way to help consumers make more informed dietary choices. The

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 79 of 93 effectiveness of labeling, however, depends largely on how consumers respond to the measure. Although the NLEA does not mandate restaurant nutrition labeling, there is a body of research that has investigated consumer responses to nutrition labeling on food away-from-home.

A number of experimental studies have examined consumer behavior in cafeteria, restaurant and vending machine settings in response to nutrition information or health messages. The results of these studies are mixed; differences in results among studies may be due to differences in experimental designs, including size of sample, demographic characteristics of participants, experimental setting, length of study, type of nutrition information or health message and type of behavioral outcome studied.

In a British college cafeteria, display of calorie and nutrient content of food items on the menu board had a negative effect, resulting in higher calorie and fat intake at lunch (Aaron et al 1995). The differences were greater for males and for less restrained eaters. The authors stated that the results indicate the importance of assessing the motivational choices of potential recipients of nutrition education programs. A second study in a British sit-down restaurant with a limited menu found fewer participants selected an entrée marked as a lower fat option, although the difference was not statistically significant (Stubenitsky et al). However, those selecting the lower fat entrée had lower calorie and fat intake both from the entrée and from the complete lunch. Sensory expectations and post-meal acceptance measures were similar for the entrée in its regular or lower fat version, both when the lower fat version was labeled and when it was unlabeled.

In a cafeteria for the general public, prominent labeling of certain items as "lower caloric selections" had no effect on calories eaten or perceived calories eaten, either among restrained eaters (dieters) or unrestrained patrons (Johnson et al 1990). Restrained eaters did choose lower calorie meals, but their choices were not related to the presence of the "lower caloric selection" label. In a college cafeteria, changes in the proportion of patrons choosing items from various food groups resulted from labeling the caloric content of food items, highlighting healthier choices with a symbol, or providing tokens for monetary incentive for healthier choices (Cinciripini). Changes in food group selection with labels or tokens were different for males and females and for lean, normal or obese participants. Overall, calorie labeling decreased the selection of starchy foods and red meat items; healthier selection labeling with incentive tokens increased the selection of vegetables/soup/fruit/lowfat dairy, chicken/fish/turkey and salads and decreased the selection of high fat/dessert/sauces. In a family-style, table-service restaurant, special healthful entrees were highlighted by rotating messages: a nonspecific message, a healthfulness message and a taste plus healthfulness message (Colby et al). Sales of the healthful chicken or tuna entrees were higher when the taste plus health message was used than with the health alone message.

One recent study compared the effect of health messages and lowered prices, separately and together, on the purchase of healthy food items in a counter-service, delicatessan-style restaurant (Horgen and Brownell 2002). Price decreases alone, rather than a combination of price decreases and health messages, were associated with increased purchases of some healthy food items over a 4-month period. The authors suggested that health messages may have paradoxical effects if foods labeled as healthy are assumed to taste bad.

Restaurant patrons at a table-service restaurant for university students and staff indicated their labeling preferences among menus using an apple symbol to highlight healthy selections, menus using colored dots to highlight specific nutrition guidelines, or a leaflet listing numeric values for nutrient content (Almanza and Hsieh). Both the apple symbol and the leaflet were preferred over the colored dots, and were considered more attractive, less time-consuming and easier to use. The apple symbol was preferred over the leaflet by women patrons and those younger or less educated. However, this study did not examine whether patron labeling preferences were related to consumption behavior. Previous FDA research has suggested that label format preference does not necessarily equate to format effectiveness (Levy, Fein, and Schucker 1992).

An experimental study, conducted by mail using a consumer household research panel of primary food shoppers, found interactions between the effects of a heart disease claim and a Nutrition Facts panel on either a package for a frozen lasagna entrée or a menu listing a lasagna entree (Kozup, Creyer, and Burton 2003). When no nutrition information was present and there was a heart disease claim on the package or menu, subjects thought that regular consumption would reduce the risks of heart disease and stroke, and the claim had a positive effect on their attitudes toward the food, its healthiness, and intention to purchase the food. Regardless of presence or absence of the heart disease claim, better nutrient content had a positive effect on perception of the food's relationship to heart disease risk as well as a positive effect on attitude toward the food, the healtfulness of the food and intention to purchase. Poorer nutrient content had corresponing negative effects. Addition of the claim to positive nutrition information further increased the perception of reduced heart disease risk, but did not increase other positive attitutes compared with nutrition information alone. Addition of the claim to negative nutrition information (inconsistent with the claim) had no effect on product evaluations and led to a negative impression of the credibility of the manufacturer or restaurant marketing the food. In a further experiment, evaluations of a menu item were affected by alternative items presented. If the nutrition information of alternative items was more favorable, then the evaluations of the item were less positive, and vice versa. This suggests that the alternative or nontarget menu items served as a reference for the target items. If the nutrition information of alternative items was present, then the positive effect of the heart disease claim was limited to perception of the food's reduction of heart disease risk.

Practical problems in restaurant labeling and obstacles to labeling as reported by large restaurant chains have been reviewed (Boger 1995, Almanza 1997). Problems include the fact that NLEA guidelines were developed for packaged foods, not restaurant food, with respect to serving sizes and criteria for health and nutrient content claims; different sized portions for lunch and dinner; variability of menu item from day to day. A suggestion for further research was whether consumers use nutrition information on packaged foods differently than in restaurants (Almanza 1997).

In summary, consumers have mixed reactions to nutrition information in cafeterias and restaurants. Both health claims and listing of nutrition information have been found to be capable of producing positive influences on consumer evaluations of menu items and the influences appear to be

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 80 of 93 strongest when nutrition information about alternative menu items is absent. Although nutrition information may influence choices and attitudes, other factors may be more salient: whether the respondent is on a diet, attitudes toward nutrition, price of food, health claim vs. nutrition information, taste/perceived taste.

Restaurant references

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Restaurant studies from the Economic Research Service

An analysis of studies received from the USDA Economic Research Service (their own and others) show that eating away from home, particularly increasing consumption in fast food restaurants, is correlated with increases in BMI. Further, the per capita number of restaurants in a state was positively related to individual's BMI and the probability of being overweight. These studies are summarized in the following charts, used courtesy of USDA ERS.

Question 1 (and 4): Correlations between BMI and Consumption of Foods Away From Home (FAFH)

Author(s)	Source	Title	Data Source	Dependent Variable	Estimated Effect of FAFH-Specific	Estimated Effect of FAFH-General
Binkley, Eales,	International	"The relation	CSFII 1994-	BMI	The average man	For men, both fast
and Jekanowski	Journal of Obesity	between dietary	1996		who was 1.77m tall	food and restaurant
	(2000) 24, 1032-	change and rising			and consumed	consumption
	1039	US obesity"			restaurant food	positively and
					was .9 kg heavier	significanlty
					than those who did	impacted BMI. For
					not eat at a	women, only FF
					restaurant. If he	consumption
					consumed food at	positively and
					FF places, he was .8	significantly
					kg heavier. The	impacted BMI.
					average women	
					who was 1.63m and	
					consumed	

FDA/CFSAN - Report of the V	Vorking Group on Obesity: Append	ix G - Reporof Market Studies O	ffice of Scientific Analysis a	nd Support, FDA CFSAN		
C	ase 1:08-cv-0100	00-RJH Docun	nent 33-6	Filed 02/15/200	Page 81 of 9 restaurant food weighed .2 kg more than a woman who did not consume FF.	93
Lin, Huang, and French	Submitted to the International Journal of Obesity	"Women's and Children's Body Mass Indices	1994-1996 and 1998 CSFII	BMI	All Women: a 1% increase in FAFH was associated with an 1.28 point increase in BMI. For high income women, this was associated with a 1.63 point increase in BMI	For all women, increasing the percent of meals consumed away from home significantly increased BMI. When seperating by income, effect was still significant for higher income women (>185% of poverty level). No such correlation for lower income women. No significant correlation for children either.
Chou, Grossman, and Saffer	"An Economic Analysis of Adult Obesity: Results from the behavioral risk factor surveillance system."	NBER: Working Paper 9247 http:// www.nber.org/ papers/w9247	1984-1999 BRFSS	Reported and Adjusted BMI	Increasing the number of restaurants was estimated to increase BMI by 1.7% and increase the probablity of being obese (PO) by 9%. Increasing the price of fast, restaurant and home food was estimated to increase BMI by .5, .2 and .35% respectively. These prices were estimated to increase the PO by 4, .7 and 3%	The per capita number of restaurants in a state was positively related to an individual's BMI and probability of being overweight. FF, Restaurant and Home Food prices were all negatively related to BMI
Kuchler and Lin	"The Influence of Individual choices and attitudes on adiposity"	International Journal of Obesity (2000) 26	CSFII 1994- 1996	BMI	All respondents: a 1% increase in FAFH was associated with an .93 point increase in BMI. For women, this was associated with a 1.24 point increase. No significant increase for men	Overall, and for women, increasing the percent of meals consumed away from home significantly increased BMI.

	Case 1:08-cv-0	1000-RJH Docun	nent 33-6	Filed 02/15/2	008 Page 82 of	93
Variyam	No title	ERS Presentation	NHANES I	BMI	Among the	Among those who
			Follow-up		individuals who	consumed >10% of
			study		consumed <=10%	cals away-from-
					of cals away-from-	home 39.3%
					home, 34.2% of	became overweight,
					healthy weight	and 18% went from
					became overweight	overweight to
					over a 20-year	healthy weight.
					period and 28%	(Note this was only
					went from	a simple bivariate
					overweight t	anaysis, so keep the
					healthy weight.	usual caveats in
						mind.)

Question 2: Are Calories From Foods Purchased Away From Home More Dense?

Author(s)	Source	Title	Data Source	Note	Dependent Variable	Calories	Fat
Lin, Guthrie, and Frazao	FoodReview, Volume 24, Issue 2	"American Children's Diets Not Making the Grade"	NCFS 1987-1988 CSFII 1994-96	See Attached Chart			
Lin, Guthrie, and Frazao	ERS Service Report	"Away From Home Foods Increasingly Important to Quality of American Diet"	NCFS 1987-1988 CSFII 1994-96	See Attached Chart			
Mancino	PhD Thesis	"American's Food Choices: The Interaction of Information, Intentions, and Convenience	CSFII 1994-1996		Per Meal Caloric Intake and Per Meal Percent of Calories From Fat	Evaluated at the sample means and using the RDI, a man who ate a meal from home, a restaurant, or a fast food restaurant consumed and average of 807, 1097 and 1041 calories at that meal. A woman consumed 503, 702, and 664 calories, respectively	Evaluated at the sample means an individual who at a meal from home, a restaurant, or a fast food restaurant consumed an estimated 24, 30, and 32 percent of his or her calories from fat
Variyam	In the works	Are Nutrition Labels Effective	CSFII 1994-1996			After adjusting for other factors, at- home food is between 360 to 540 calories/kg less dense than FAFH	

Comparison of Total Calories and Caloric Density of Foods Prepared At Home and Food Prepared Away From Home

1987-1988	1995

	Average Intake	1:08-cv-01 Benchmark	At Home	Away From Home	Restaurant	Fast- Food	Average Intake	2/15/2008 Benchmark	At Home	83 of 9 Away From Home	Restaurant	Fast- Food
Calories	1876	*	1369.48	506.52	93.8	93.8	2043	*	1348.38	694.62	163.44	245.16
Percent of Calories From Fat	37	30	36.3	38.7	41.3	39.7	33.6	37	30	37.6	40.1	39.3
Percent of Calories from Saturated Fat	13.8	10	13.5	14.7	15.5	15.4	11.5	10	10.9	12.8	12.5	13.8
Milligrams of Cholesterol per 1000 calories	286	166	161	151	215	138	268	147	129	134	176	124
Milligrams of Sodium per 1000 calories	1672	1328	1678	1656	1824	1575	1637	1175	1630	1651	1873	1674
Grams of Fiber per 1,000 calories	7	10.7	7.5	5.8	5.8	5	7.4	10.4	8.1	6.1	6.2	5.6

Comparison of Total Calories and Caloric Density of Foods Prepared At Home and Food Prepared Away From Home (Cont.)

			1987-19	988					1994-19	96		
	Average Intake	Benchmark	At Home	Away From Home	Restaurant	Fast- Food	Average Intake	Benchmark	At Home	Away From Home	Restaurant	Fast- Food
Percent of Total Calories			80	20	11	2	*	*	68	32	4	10
Percent of Calories From Fat	35.93	30	35.2	38	40.5	38.8	32.99	30	31.6	36.1	38.1	36.3
Percent of Calories from Saturated Fat	13.39	10	13	14.5	15.2	15.2	12.01	10	11.5	13.2	12.5	13.6
Milligrams of Cholesterol per 1000 calories	143	170	149	129	176	125	115	153	118	106	142	101
Milligrams of Sodium per 1000 calories	1616	1363	1637	1561	1674	1484	1575	1222	1570	1588	1721	1621
Grams of Fiber per 1,000 calories	6.4	8.2	6.6	6.2	5.2	4.9	6.7	7.3	6.9	6.2	6.2	5.6

Case 1:08-cv-01000-RJH

Document 33-6

Filed 02/15/2008

Page 84 of 93

Sample: Children aged 2-17

Source: Lin, Guthrie, and Frazao 2001

Appendix B. Sample Annotated Bibliography Entries

Authors: Kim, Sung-Yong, Rodolfo M. Nayga, Jr., and Oral Capps, Jr.

Date: July 2000

Title: The Effect of Food Label Use on Nutrient Intakes: An Endogenous Switching Regression Analysis

Citation: Journal of Agricultural and Resource Economics 25(1): 215-231.

Relevance: HIGH

Focus

Kim et al. (2000) look at the impact that use of nutrition labeling has on five nutrient intakes (calories from total fat, calories from saturated fat, cholesterol, dietary fiber, and sodium). They use data from the 1994-1996 Continuing Survey of Food Intakes by Individuals (CSFII) and the Diet and Health Knowledge Survey (DHKS). They control for self-selection to use labels with an endogenous switching regression model. Use of the endogenous switching regression model allows them to also look at factors that influence label usage.

Data

As noted, the data comes from the 1994- 1996 CSFII and DHKS. They use observations on 5,203 individuals that completed both the day-1 and day-2 surveys and that had complete data otherwise. No indication is given of the sample size relative to the total sample.

In forming the variable that measures label use, they convert a four-point scale to a binary yes/no variable. Respondents were asked about their frequency of label use for each of the five nutrients studied in the analysis. They were given four response options: "often," "sometimes," "rarely," and "never." Kim et al. convert "often," "sometimes," and "rarely" responses into "yes" answers and "never" responses into "no" answers. This differs from the mapping used by Guthrie et al. (1995).

Statistical Methodology

The switching regression framework employed by Kim et al. is a standard application of this method. Maddala (1983, Section 8.3) provides a treatment of this method. In brief, the model involves estimating separate regressions for label users and non-users for each of the five nutrients. A third equation that uses the label use decision as a dependent variable is also estimated. The three equations (nutrient intake for label users, nutrient intake for label non-users, and the decision to use labels) are not independent and have non-zero correlations across the error terms. The system is estimated using full information maximum likelihood.

To estimate the impact that food labels have on nutrient intakes, Kim et al. follow a standard method employed in switching regression models. First, they calculate the predicted values for nutrient intakes for label users. This is done for each nutrient using the label user equation. Next, they calculate the predicted values of nutrient intakes for label users using the label non-users' equation. That is, they take the label users and generate predicted values for nutrient intakes using the label non-users equation. The difference in the mean values of these predicted values represents the impact of label use on nutrient intake.

Results

The results of their statistical analyses indicate that label use has beneficial impacts for each nutrient. The use of labels is associated with: $(\frac{28}{})$

- A 16.1 percent decrease in the intake of calories from fat;
- A 15.1 percent decrease in the intake of calories from saturated fat;
- A 21.0 percent decrease in the intake of cholesterol;

Case 1:08-cv-01000-RJH Document 33-6

• An 87.1 percent increase in the intake of dietary fiber; and

Filed 02/15/2008

Page 85 of 93

• A 0.9 percent decrease in the intake of sodium.

None of the estimated impacts were judged for their statistical significance, even though this is possible in a switching regression model.

Kim et al.'s analysis also look at the factors that influence label use. They find that income, education, a good knowledge of diet-health issues, being on a special diet, exercising regularly, and being the family meal planner are all positively associated with label use. Factors that are negatively associated with label use include: household size, age, being male, living in a non-metropolitan area, using food stamps, and being a smoker.

Relation to CFSAN Study

This study is **highly relevant** for the CFSAN study.

- The study focuses on the same issues that the CFSAN study will look at: how does use of labels affect nutrient intakes and what factors influence use of labels.
- The study uses the same data that will be used in the CFSAN analysis.
- We anticipate use of a similar method as is used in this analysis.

Comments

- The study looks at five nutrient intakes, which are likely to be related to one another. The method, however, does not attempt to account for any cross-equation relationships. We suggest that a seemingly unrelated regression (SUR) framework be investigated for use in combination with this method to capture cross-equation relationships.
- The use of a binary variable for label use may be too simplistic. We expect that more than three categories can be specified: "always uses labels," "sometimes or rarely uses labels," and "never uses labels." This would complicate the switching regression framework, but not to an unmanageable degree. This would also allow CFSAN to look at how influencing consumers that are "never" users to become "sometimes" users would affect nutrient intakes. Additionally, CFSAN could look at how influencing "sometimes" users to become "always" users would affect nutrient intakes.
- The statistical method does not appear to account for sampling weights.
- Restricting to respondents that are in both the day-1 and day-2 survey may result in sample selection that is uncontrolled by the switching regression framework.

Closely Related

Guthrie et al., 1995

Authors: Guthrie, Joanne F., Jonathan J. Fox, Linda E. Cleveland, and Susan Welsh

Date: July-August 1995

Title: Who Uses Nutrition Labeling, and What Effects Does Label Use Have on Diet Quality?

Citation: *Journal of Nutrition Education* 27(4): 163-172.

Relevance: HIGH

Focus

Guthrie et al. (1995) look at the impact of the use of food labels on the intake of 26 food components (e.g., protein, total dietary fat, etc.). They use data from the 1989 Continuing Survey of Food Intakes by Individuals (CSFII) and the Diet and Health Knowledge Survey (DHKS). They control for self-selection to use labels with Heckman's self-selection model. As part of their analysis, they also examine factors that influence the use of food labels.

Case 1:08-cv-01000-RJH

Document 33-6

Filed 02/15/2008

Page 86 of 93

Data

The study uses data from the 1989 CSFII and DHKS. Their sample consists of 1,901 individuals that responded to the DHKS portion of the survey. The 1989 CSFII was designed to collect three days of food consumption data from respondents. The first day was (day-1) was collected using the 24-hour recall method (i.e., "What did you eat in the last 24 hours?"). The second and third day data were collected through a 2-day food record. Guthrie et al. only use the day-1 data in this study. They note that 1,548 respondents (of the 1,901 that completed the DHKS) submitted a full three days of food consumption data. Their reason for using the day-1 data only is to maintain sample size.

The study uses sampling weights in the statistical analysis, when appropriate. The sample design for the CSFII/DHKS calls for over-sampling of low-income households. Thus, the use of sampling weights in the analysis controls for the survey design.

In forming the variable that measures label use, Guthrie et al. convert a four-point scale into a binary yes/no variable. Respondents were asked about their frequency of label use for each of the five nutrients studied in the analysis. They were given four response options: "often," "sometimes," "rarely," and "never." Guthrie et al. convert "often" and "sometimes" responses into "yes" answers and "rarely" and "never" responses into "no" answers. This differs from the mapping used by Kim et al. (2000).

Statistical Methodology

The authors follow Heckman's standard model of self-selection to generate the coefficient estimates. In their analysis, individuals self-select to use nutrition labels. They first estimate a probit model for label use and then calculate the inverse mills ratio for each individual in the data. The inverse mills ratio is then added to the regression models that use the 26 food components as dependent variables. They estimate only one label-use equation rather than one for each food component. This differs from the Kim et al. (2000) study, where a separate label use equation was estimated for each of the five nutrient intakes investigated.

The basic regression equation for the food components regresses the amount of the food component on a set of explanatory variables that includes a zero-one binary variable for label use. The addition of the inverse mills ratio to the equation controls for self-selection to use labels.

One interesting aspect of this study is its use of principal components analysis (PCA) to pare down the number of variables that reflect individuals' "attitudes and values" that guide them in making food choices. The DHKS asks a number of questions regarding the individuals' preferences for either avoiding or ensuring the consumption of various food components. Inclusion of all of these variables in a regression framework would lead to significant multicollinearity. Using PCA, the authors are able to reduce the number of variables that reflect food choice values to two factors, thereby overcoming the multicollinearity problem.

Results

In the article, the authors only present the estimated coefficient for the zero-one binary variable for label use and the coefficient for the inverse mills ratio rather than the full regression model results (26 equations). For the 26 equations, only two show a significant impact of label use: higher intake of Vitamin C and lower intake of cholesterol. Additionally, self-selection only appears to be an issue for Vitamin C and cholesterol intakes.

Relation to CFSAN Study

This study is **highly relevant** for the CFSAN study.

- The study focuses on the same issues that the CFSAN study will look at: how does use of labels affect nutrient intakes and what factors influence use of labels.
- The study uses the same, but earlier, data that will be used in the CFSAN analysis.
- We anticipate use of a similar method as is used in this analysis.

Comments

- The study looks at 26 nutrient intakes, which are likely to be related to one another. The method does not attempt to account for any cross-equation relationships. We suggest that a seemingly unrelated regression (SUR) framework be investigated for use in combination with this method to capture cross-equation relationships.
- The use of 26 nutrient intakes is very broad. It appears that this restricts what they can say on any one nutrient intake.

The study's use of a binary variable for label use may be too simplistic. We expect that three categories can be specified: "always uses labels," "sometimes or rarely uses labels," and "never uses labels."

- Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 87 of 93

 Restricting the sample to the day-1 data only may influence the results to an unknown degree. The use of day-1 data only was based on maintaining sample size. Restricting the sample to individuals with three days of data may also result in bias, however. Nevertheless, it may be possible to develop a panel analysis (individuals over days) that accounts for sample attrition (i.e., individuals that do not provide day-2 or day-3 data). This would expand the nutrient intake data.
- The results are not convincing that labels influence diet. Only two of the 26 food components, or eight percent of the regressions, have a significant coefficient for label use. At a five percent level of significance we can expect to be "wrong" about a statistical inference five percent of the time. This set of results comes close to that critical cut-off. More convincing results would involve a significant coefficient in one-third or more of the regressions.
- Not providing the full regression results limits our ability to fully assess this study. It would be interesting to see the signs and significance of all other variables included in the analysis.

Closely Related

Kim et al. (2000)

Appendix C. Sample Pages from Spreadsheet of Restaurant Web Sites

Sample Page One from Spreadsheet of Restaurant Web Sites

				Nutrition info available online				
Restaurant number	Name	Description	Website	Interactive	pdf or html	"light" but no nutritional info		
1	McDonald's	Fast Food	http://www.mcdonalds.com/countries/usa/food/nutrition/categories/nutrition/index.html	yes	yes	no		
2	KFC	Fast Food	http://www.yum.com/nutrition/menu.asp? brandID_Abbr=2_KFC	yes	yes	no		
3	Pizza Hut	Casual Dining	http://www.yum.com/nutrition/documents/ph_nutrition.pdf	yes	yes	no		
4	Taco Bell	Fast Food	http://www.yum.com/nutrition/menu.asp? brandID_Abbr=5_TB	yes	yes	no		
5	A&W	Fast Food	http://www.yum.com/nutrition/menu.asp? brandID_Abbr=4_AW	yes	yes	no		
6	Long John Silver	Fast Food	http://www.yum.com/nutrition/menu.asp? brandID_Abbr=3_LJS	yes	yes	no		
7	Au Bon Pain	Fast Food	http://www.aubonpain.com/	yes	yes	no		
8	RED LOBSTER	Casual Dining	http://www.redlobster.com/homeflash.asp	no	no	no		
9	Olive Garden	Casual Dining	http://www.olivegarden.com/ourmenus/garden_fare.asp	no	yes	no		
10	Bahama Breeze	Casual Dining	http://www.bahamabreeze.com/food.html	no	no	no		
11	Smokey Bones Bar-b-q	Casual Dining	http://www.smokeybones.com/menu/sb_menu.pdf	no	no	no		
12	Starbucks	Coffee shop	http://www.starbucks.com/retail/nutrition_freshfood.asp	yes	no	no		
13	Chili's Grill & Bar	Casual Dining	http://www.chilis.com/menu/default.asp? catID=7&tierID=29&Unit_ID=701%2E010% 2E0006&menuType=Dine+In	no	yes	no		
14	Romano's Macaroni Grill	Casual Dining	http://www.macaronigrill.com/menu/default.asp? Unit_ID=001%2E009% 2E0079&tierID=18&menuType=Lunch&menu=1	no	no	no		

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 88 of 93 On The http://www.ontheborder.com/menu/default.asp? Border 15 Casual Dining catID=&tierID=28&Unit_ID=750%2E710% no no no Mexican Grill 2E0001&state=VA & Cantina Maggiano's http://www.maggianos.com/menu/default.asp? 16 Casual Dining no no no Little Italy Unit_ID=001.025.0071 Corner 17 Fast Food http://www.cornerbakery.com/default.asp no no no Bakery Cafe, Cozymels http://www.cozymels.com/menu/default.asp?Unit_ID=001% 18 Casual Dining Coastal no no no 2E019%2E0033&tierID=16&menuType=Dine+In&menu=1 Mexican Grill Big Bowl 19 Casual Dining http://www.bigbowl.com/menu/BIGBOWL_Menu_VA.pdf no no no Asian Kitchen Rockfish 20 Casual Dining http://www.rockfishseafood.com/ no no no Seafood Grill. 21 Wendy's Fast Food http://www.wendys.com/food/index.jsp yes yes no 22 Sbarro Fast Food http://www.sbarro.com/ no no no Coffee and 23 Krispy Kreme http://www.krispykreme.com/nutri.pdf no yes no Doughnuts Outback 24 Casual Dining http://www.outback.com/menu/menuprinterfriendly.asp no no no Steakhouse Flemings 25 Casual Dining http://www.flemingssteakhouse.com/sides.html no no no Steak House 26 Roy's Upscale http://www.roysrestaurant.com/docs/about_frames.html no no no

Sample Page Two from Spreadsheet of Restaurant Web Sites

	NI4:4:	: C-	1					et of Restaurant Web	
Restaurant	Nutriti	on into	avan	abie in r	estaurant *		nutr	ition info coverage	
number	menu board	menu	tray	napkin	brochure	other	all items	info on partial or targeted items	Notes
1					yes			yes	nutritional info for most popular items, food exchanges and recommendations
2							yes	yes	Additional healthier options menu
3							yes	yes	Info on healthier choices
4							yes	yes	Additional info on Fresco or lower cal stuff
5							yes	yes	Info on healthier choices
6							yes	yes	Lower calorie suggestionsleave out the sour cream or tartar sauce, etc.
7							yes	yes	Interactive Menu, lots of info and special nutrition info.
8									Online menu with no nutrition info
9		yes						yes	nutrition info on Garden Fare stuff only.
10									Online menu with no nutrition info
11									Online menu with no nutrition info
12					maybe				
13		yes						yes	Guiltless Grill menu (in restaurant has fat but no calorie info)
14									Online menu with no nutrition info
15									Online menu with no nutrition info
16									Online menu with no nutrition info

	Case 1	:08-c\	/ - 010	000-RJ	H Do	cume	nt 33-6	Filed 02/15/200	8 Page 89 of 93
17									Online menu with no nutrition info
18									Online menu with no nutrition info
19									Online menu with no nutrition info
20									Online menu with no nutrition info
21					maybe		yes	yes	Interactive Menu, lots of info and special nutrition info.
22									Under construction -menu not available
23									Hard to find nutrition page. Uses packaged food format for labeling nutritition info
24									
25									Online menu with no nutrition info
26									Online menu with no nutrition info

(28) Estimated percentages reflect our conversion of results reported in Table 5 of the paper to percentage numbers. In calculating these, we divided the "Before Using Nutrition Label" column by the "Net Change" column for the "Average Nutrient Intakes."

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March 12, 2004

Appendix H - Developing Effective Consumer Messages

The Food and Drug Administration's (FDA) Obesity Working Group Report

Effective consumer health messages about weight management and obesity prevention should be research-based and take into account the values, beliefs, motivations, needs and behaviors that comprise the "consumer reality" of the target audience. It is important that these messages be clear, simple, and understandable and do not undermine the credibility and impact of public health agencies.

There are six key questions to consider when developing research-based messages that encourage knowledge utilization:

- 1. What is the purpose?
- 2. Who is the target?
- 3. What is the promise (i.e., motivators)?
- 4. What is the support?
- 5. What is the image?
- 6. Where are the best opportunities for delivering the messages?

In determining the target audience(s) for research-based messages, it is important to consider that communication theory holds that more direct, population subgroup-focused messages typically have greater impact than messages that address a wider audience (e.g., the general public). At the same time, overweight and obesity have been identified as a national health problem, so it seems important to develop focused messages that affect large population subgroups.

Among private sector organizations, IFIC has been prominent in recent efforts to develop effective nutritional messages. IFIC uses a five-part system (Borra *et al.*, 2003):

- 1. Defining the relevant issues
- 2. Developing the initial message(s)
- 3. Examining candidate messages in focus groups
- 4. Refining the messages
- 5. Validating the messages in quantitative surveys

IFIC has drawn a number of conclusions from its efforts, many of which are supported by other researchers

FDA/CFSAN - Report of the Working Group on Obesity: Appendix H - Developing Effective Consumer Messages

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 91 of 93 (Marietta *et al.*, 1999; Kennedy and Davis, 2000; Borra *et al.*, 2001; Patterson *et al.*, 2001; Balasubramanian and Cole, 2002; Ikeda *et al.*, 2002; Gans *et al.*, 2002; Borra *et al.*, 2003; Gans *et al.*, 2003; IFIC 2003):

- 1. Consumers will not react positively to messages unless the messages set forth concrete goals that consumers view as achievable.
- 2. Consumers perceive general nutrition guidelines as too abstract and requiring too much planning and calculation to translate into action.
- 3. Consumers are receptive to messages that make direct, concrete suggestions and therefore provide tools with which consumers may exercise choice. Consumers resist being told what they must do.
- 4. Goals should be incremental rather than monolithic so that consumers can receive continuous positive feedback. Concrete and incremental goals sustain and reinforce consumers' desire for autonomy. Equally important is that setting and achieving incremental goals provides more opportunities for reinforcement (both self and external), which is important for sustaining positive behaviors. Consumers view monolithic goals as unrealistic because they would have to make substantial changes in diet and habits.
- 5. Overemphasis on one or a few nutritional components of a diet may impede the overall goal of achieving a healthy, varied diet.
- 6. Health and nutrition messages should be developed with an awareness of the varied cultural backgrounds found among the American public; different ethnic and cultural groups exhibit different dietary patterns and practices.

In qualitative studies, consumers claim they do not wish to spend a significant amount of time reading and comprehending labels. This is borne out by the fact that many use health or nutrient content claims as indicators as to the overall quality of the product and do not check the nutrition facts panel on the back (Roe, *et al.*, 1999). Also, consumers appear to be confused by serving sizes, particularly by multiple servings listed on small packages, as well as by the %DV listed in the nutrition facts panel. Consumers use food labels for multiple reasons, including diet plans and pre-existing health conditions such as diabetes and heart disease, and look for macronutrients of concern. On the other hand, taste, convenience, price, mood and family preferences influence purchases and are often at odds with healthy eating. Such factors present challenges for developing effective messages.

Other findings indicate that adults do not like "diets" and do not believe they work over the long term (Borra et al., 2003). They also question whether there is any new nutrition information that they will find useful. Also, the qualitative studies found that encouraging parents and children to work together resonated, as did messages promoting better appearance ($\frac{29}{2}$) and self-esteem. Consumers need to hear new kinds of information, or a repackaging of old information in new and relevant ways, that will serve as "motivation to jumpstart new thinking and behaviors."

Notes:

FDA/CFSAN - Report of the Working Group on Obesity: Appendix H - Developing Effective Consumer Messages

Case 1:08-cv-01000-RJH Document 33-6 Filed 02/15/2008 Page 92 of 93

²⁹ At this time, FDA does not intend to use "better appearance" as a motivator for any of its obesity messages, given the larger concern about the effect such a focus may have on those with eating disorders (e.g., anorexia and bulimia).

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FDA Home Page | CFSAN Home | Search/Subject Index | Q & A | Help

March 12, 2004

Counting Calories Report of the Working Group on Obesity

Appendix I Power of Choice

Table of Contents

The Power of Choice is an after-school program developed jointly by FDA and USDA's Food and Nutrition Service. The materials guide pre-teens toward a healthier lifestyle by motivating and empowering them to make smarter food and physical activity choices in real-life settings. A Leader's Guide, containing ten sequenced interactive sessions engage adolescents in fun activities that develop skills and encourage personal development related to choosing foods wisely, preparing foods safely, and reducing sedentary behaviors. Most activities require little or no pre-planning and are simple to do. The Leader's Guide also includes easy snack recipes, 170 Nutrition Facts cards, and posters on four key topics, and a computer disk provides supplemental activities to each of the 10 sessions, a self-training video for the leader, community support suggestions, and much more.

Current status: Currently, the Power of Choice is being distributed either in hard copy or it can be downloaded on the Team Nutrition Web site, USDA's Food and Nutrition service (http://www.cfsan.fda.gov/~dms/lab-poc.html). Of the original 15,000 copies published, less than 4,000 copies remain for free distribution to those belonging to USDA's Child Nutrition Programs (includes schools). Response from users has been virtually unanimously positive: "One of the best government products I've seen in a long time"; "I love this material. Please send me more"; "I think it's great! Exciting!! I've been needing something like this - thank you for doing such a great job".

Food Labeling and Nutrition | Calories Count

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Patterns and Trends in Food Portion Sizes, 1977-1998

Samara Joy Nielsen

Barry M. Popkin, PhD

LTHOUGH GENERAL CONSENsus holds that food portions have been increasing and that this increase is one factor contributing to the obesity epidemic in the United States, no empirical data to date have documented actual increases. 1 One recent study showed that most commonly available food portions exceeded the US Department of Agriculture (USDA) and Food and Drug Administration (FDA) standard portion sizes and that most foods are available in larger portion sizes than they were in the 1970s.2 Another small study reported portion size increases for meat portions but not for other foods, whereas 2 studies have linked portion size increases to increased total energy intake.3-5 The portion size changes are part of the "supersizing" phenomenon seen at fast food establishments and at restaurants.6

In this study, we used nationally representative dietary intake data to determine patterns and trends in portion sizes by type of food and eating location and to compare portion sizes eaten outside the home with those eaten at home.

METHODS

This study used data on individuals aged 2 years and older from 3 nationally representative surveys of the US population (N=63380): 29695 for the National Food Consumption Survey 1977 (NFCS77)⁷ and 14658 for the Continuing Survey of Food Intake for Individuals 1989 (CSFII89)⁸ and 19027 for 1996 (CSFII96).⁹ The CSFII96 survey also included a sample of children aged 2 to 9

Context While general consensus holds that food portion sizes are increasing, no empirical data have documented actual increases.

Objective To determine trends in food portion sizes consumed in the United States, by eating location and food source.

Design, Setting, and Participants Nationally representative data from the Nationwide Food Consumption Survey (1977-1978) and the Continuing Survey of Food Intake by Individuals (1989-1991, 1994-1996, and 1998). The sample consists of 63 380 individuals aged 2 years and older.

Main Outcome Measure For each survey year, average portion size consumed from specific food items (salty snacks, desserts, soft drinks, fruit drinks, french fries, hamburgers, cheeseburgers, pizza, and Mexican food) by eating location (home, restaurant, or fast food).

Results Portion sizes vary by food source, with the largest portions consumed at fast food establishments and the smallest at other restaurants. Between 1977 and 1996, food portion sizes increased both inside and outside the home for all categories except pizza. The energy intake and portion size of salty snacks increased by 93 kcal (from 1.0 to 1.6 oz [28.4 to 45.4 g]), soft drinks by 49 kcal (13.1 to 19.9 fl oz [387.4 to 588.4 mL]), hamburgers by 97 kcal (5.7 to 7.0 oz [161.6 to 198.4 g]), french fries by 68 kcal (3.1 to 3.6 oz [87.9 to 102.1 g]), and Mexican food by 133 kcal (6.3 to 8.0 oz [178.6 to 226.8 g]).

Conclusion Portion sizes and energy intake for specific food types have increased markedly with greatest increases for food consumed at fast food establishments and in the home.

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years surveyed in 1998, which was designed to be merged with the CSFII96.

The USDA surveys from 1977 and 1989 contained stratified area probability samples of noninstitutionalized US households in the 48 contiguous states, and the 1996 survey included samples from all 50 states. All 3 surveys were self-weighting and multistage. The sample weights compensate for unequal selection probabilities and nonresponse as well as sampling variability, and these were designed to achieve the specified sample sizes for various sex-age-income domains. Each survey year and the combination of the multiyear surveys were designed to be nationally representative. Detailed information about each survey has been published previously.7-9

The NFCS77 and CSFII89 surveys collected 1 day of food intake by inhome, interviewer-administered, 24-hour recall and 2 days of self-administered, 1-day food records. The CSFII96 collected 2 nonconsecutive, interviewer-administered, 24-hour food recalls approximately 10 days apart by telephone. For each food consumed, the respondent was asked whether the eating occasion was a meal or a snack and where the food was obtained. If the food was bought in a store, the respondent was asked whether the food was

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 Table 1. Trends in Energy Intake by Eating Location and Key Food for Americans Aged 2 Years and Older 12*

	Total	I Energy Cons	umed	Energy	in Meals Cor	sumed	Energy in Snacks Consumed			
	1977-1978	1989-1991	1994-1996	1977-1978	1989-1991	1994-1996	1977-1978	1989-1991	1994-1996	
Key foods, %†	18.1	23.6	27.7	14.3	19.7	22.8	46.4	51.0	50.8	
At home, %	76.9‡§	72.6‡	64.5§	77.0‡§	72.3‡	63.8§	76.0‡§	74.8‡	67.4§	
Total energy, kcal	1791§	1795	1985§	1588‡§	1559‡	1634§	203‡§	236‡	351§	

brought into the home and if so, whether it was eaten at home. These data were then used to classify food sources into the 4 following categories: (1) eaten or prepared at home, (2) from a fast food establishment, (3) from a restaurant, or (4) from any other source. Other than food that was bought from a store, food from any other source was considered to be from that source even if brought into the home.

To examine the thousands of foods contributing to energy intake, the foodgrouping system¹⁰ from the University of North Carolina at Chapel Hill was used in this study. This system aggregates all foods in the USDA nutrient composition tables into 74 descriptive and nutrient-based subgroups. In addition, selected popular foods, such as pizza, hamburgers, and french fries, were identified to examine trends in energy intake over time. These foods had been identified in a previous study that examined trends in fat intake.11

The foods chosen for this study were those identified as having the greatest kilocalorie changes in Americans' diets between 1977 and 1996.12 These key foods combined represented 18.1% of all kilocalories consumed in 1977-1978 and represented 27.7% of all kilocalories consumed in 1994-1996 for Americans aged 2 years and older (TABLE 1). While 77% of total kilocalories were consumed at home in 1977-1978, this decreased to 65% of total kilocalories consumed at home in 1994-1996 for Americans aged 2 years and older. During this same period, meals have decreased from approximately 89% of total kilocalories consumed to 81% of kilocalories consumed, and snacks have increased by

those 7 percentage points for Americans aged 2 years and older.12 As previously reported, intakes of medium-fat and high-fat beef and pork products and high-fat luncheon meats and hot dogs have decreased, probably related to increasing amounts of cheeseburgers, pizza, and Mexican food being consumed, and this is consistent with a shift from medium-fat and high-fat meat items to medium-fat and high-fat mixed grain dishes.13

The USDA data show each food item consumed, along with the self-reported eating occasion and the self-reported location where food was obtained and eaten. For each survey year, the average consumption of selected food categories (ie, salty snacks, desserts, soft drinks, fruit drinks, hamburgers, cheeseburgers) and other selected food groups (ie, pizza, Mexican food) and the eating location (ie, at home, restaurant, fast food establishment) were determined for each of the following age groups: 2 to 18 years, 19 to 39 years, 40 to 59 years, and 60 years and older). The food category salty snacks included crackers, potato chips, pretzels, puffed rice cakes, and popcorn. The food category desserts included ice cream, pies, cakes, and cookies. Mexican food included burritos, enchiladas, tacos, tostadas, and similar products.

Food consumption was estimated in 2 ways: as energy intake in kilocalories and amount consumed in ounces (0.035 oz=1.0 g). Average portion sizes were calculated using reported portion sizes of each food at 1 meal or snack. Food models are used to assist respondents in identifying the size of a portion. However, there is wide variability in re-

ported portion size, that is, based on individual specification of amount consumed. These data do not reflect cumulative amount of foods consumed by individuals during the course of a day because these data were examined on an individual meal basis. Thus, these were per-consumer averages, not per capita averages, and were intended to show changes over time in the average portion size for those who consume a specific item, not that the number of individuals consuming an item has changed. All analyses used the 1994-1996 updated nutrient database. 10 To test for statistical differences, SAS version 8.1 (SAS Institute Inc, Cary, NC) and SUDAAN 7.5.6 (Research Triangle Park, NC) software packages were used, which also allowed for weights and control of sample design effects. $P \le .01$ was set for statistical significance.

RESULTS

Between 1977 and 1996, portion sizes and energy intake increased for all key foods (except pizza) at all locations examined for the total US population aged 2 years and older surveyed (TABLE 2). During this 19-year period, the quantity of salty snacks increased by 93 kcal (0.6 oz), soft drinks by 49 kcal (6.8 oz), hamburgers by 97 kcal (1.3 oz), french fries by 68 kcal (0.5 oz), and Mexican dishes by 133 kcal (1.7 oz).

Portion sizes of certain foods increased more than others. Between 1977 and 1996, the average energy intake and portion size of salty snacks increased from 132 to 225 kcal (1.0 to 1.6 oz); the average soft drink consumed increased from 144 to 193 kcal (13.1 to 19.9 fl oz), and the average cheese-

^{*}Adjusted for age, sex, education level, race/ethnicity, region, urban classification, household size, and percentage at poverty level. †Combined percentage that salty snacks, desserts, soft drinks, fruit drinks, french fries, hamburgers, cheeseburgers, pizza, and Mexican food contribute to that segment of the

[‡]A significant difference between 1977-1978 and 1989-1991, P≤.01.

SA significant difference between 1977-1978 and 1994-1996, *P*≤.01 IIA significant difference between 1989-1991 and 1994-1996, *P*≤.01.

		Home			Restaurant	t		Fast Food			Total	
	1977- 1978	1989- 1991	1994- 1996									
					Energy	Intake, kc	al					
Salty snacks	127†‡	189†§	206‡§	113‡	150	178‡	160‡	185	249‡	132†‡	199†§	225‡§
Desserts	302‡	315	324‡	259‡	280	306‡	277†	331†	302	316†‡	334†§	357‡§
Soft drinks	130‡	133§	158‡§	125‡	126§	155‡§	131†‡	143†§	191‡§	144†‡	157†§	193‡§
Fruit drinks	137†‡	149†§	181‡§	133‡	125§	201‡§	147‡	135§	210‡§	139†‡	152†§	189‡§
French fries	196†‡	240†	236‡	168†‡	229†	222‡	171†‡	260†§	284‡§	188†‡	247†	256‡
Hamburgers	390	397	608	362	335	362	419‡	414§	497‡§	389‡	392§	486‡§
Cheeseburgers	405‡	465	542‡	381	425	485	406†‡	564†	537‡	397†‡	544†	533‡
Pizza	493†	591†§	506§	628	571	516	538	603§	503§	487†	556†§	476§
Mexican food	452‡	509	559‡	396	448	495	410‡	431§	594‡§	408‡	446§	541‡§
					Portio	on Size, oz						
Salty snacks	1.0†‡	1.4†§	1.5‡§	0.8‡	1.1	1.3‡	1.2‡	1.3§	1.9‡§	1.0†‡	1.4†§	1.6‡§
Desserts	4.2	4.2	4.4	4.0	4.3	4.5	3.9†‡	4.7†	5.2‡	4.5‡	4.5	4.8‡
Soft drinks	12.2†‡	14.7†§	17.0‡§	10.8†‡	13.6†§	15.7‡§	10.9†‡	14.0‡§	17.7†§	13.1†‡	16.8†§	19.9‡§
Fruit drinks	11.3†‡	12.4†§	14.7‡§	9.7‡	9.5§	14.4‡§	10.4‡	11.8§	15.4‡§	11.3†‡	12.6†§	15.1‡§
French fries	3.6†	4.2†	3.9	2.3†‡	3.1†	3.1‡	2.1†‡	3.0†§	3.3‡§	3.1†‡	3.5†	3.6‡
Hamburgers	5.7	5.7	8.4	5.3	4.9	5.0	6.1‡	6.3	7.2‡	5.7‡	5.9§	7.0‡§
Cheeseburgers	5.8‡	6.4	7.4‡	5.5	5.7	6.8	5.9†‡	7.7†	7.3‡	5.8†‡	7.4†	7.3‡
Pizza	6.2†	7.6†§	6.5§	7.9	7.4	6.8	6.8	7.8§	6.5§	6.2†	7.1†§	6.1§

^{*}Weighted to be nationally representative for each time period. To convert ounces to grams, divide by 0.035, and to convert fluid ounces to milliliters, multiply by 29.57.

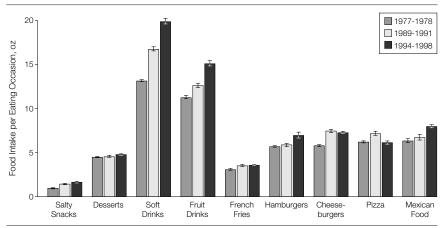
7.9±

7.0

6.0#

Figure 1. Portion Sizes for Selected Key Food Items for Americans Aged 2 Years and Older, 1977-1996

 $6.0 \pm$



Error bars indicate SE.

Mexican food

burger from 397 to 533 kcal (5.8 to 7.3 oz) (Table 2 and FIGURE 1).

Overall portion sizes for all of the selected foods, other than pizza, increased. There were no differing trends within age groups that were statistically significant; however, there are age group differences, particularly for the 60-year-olds. For people aged 2 to 18

years, hamburger portion sizes in restaurants decreased. For people aged 60 years and older, portion sizes for soft drinks decreased. Additional information for specific age groups can be obtained from the authors.

In 1994-1998, the largest portion sizes for most foods were found at fast food establishments, including salty snacks, soft drinks, fruit drinks, french fries, and Mexican food (Table 2 and Figure 2). For desserts, hamburgers, and cheeseburgers, the largest portion sizes were found at home. Consistently, restaurant portion sizes were smaller across all key foods except pizza.

 $6.3 \pm$

6.7§

8.0±§

COMMENT

8.2‡

This study provides evidence to support the general consensus that there is a marked trend toward larger portion sizes in the United States. Between 1977 and 1996, both inside and outside the home, portion sizes increased for salty snacks, desserts, soft drinks, fruit drinks, french fries, hamburgers, cheeseburgers, and Mexican food. Pizza portions in general decreased during this period. The size of the increases are substantial. Since an added 10 kcal per day of unexpended energy is equivalent to an extra pound (0.45 kg) of weight per year, it is easy to see the potential impact of large increases in portion sizes that ranged from 49 to 133 kcal (0.3 to 1.7 oz in weight; 3.8 to 6.8 fl oz) per item for com-

A significant difference between 1977-1978 and 1989-1991, $P \le .01$. ‡A significant difference between 1977-1978 and 1994-1996, $P \le .01$.

[§]A significant difference between 1989-1991 and 1994-1996, $P \le .01$.

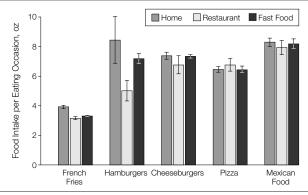
monly consumed items, such as salty snacks, soft drinks, hamburgers, french fries, and Mexican food.

Some potential limitations of our study are that the USDA changed its methods for collecting dietary data14,15 and that persons who are overweight most likely underreport their energy intake,14-18 with the extent of underreporting having increased over time. 19 There is no information to date in the United States to indicate systematic bias in reporting by eating location. Furthermore, due to increasing underreporting, the estimates of portion size are most likely smaller than the actual portion sizes being consumed. Thus, we believe that the trends in eating behavior highlighted in this article are representative of those occurring among the US population. The USDA is no longer conducting its survey; the last one conducted was the CSFII96. The survey has been combined with the National Health and Nutrition Examination Survey7-9 and currently there are no comparable data. The next comparable data set is being collected in 2002-2003. The data presented are most likely underestimations of current portion sizes.

Our study also identifies salient differences in portion size by food location. For most of the selected foods, fast food establishments served the largest and restaurants the smallest portion sizes. This might relate to fast food establishments' pricing practices of "value adding" whereby they offer much larger portions for a minor cost increase, and in some cases it is less expensive to eat larger portions in value packages than smaller portions. At the same time, the most surprising result is the large portion size increases for food consumed at home—a shift that indicates marked changes in eating behavior in general.

These findings suggest that the public requires better education about control of portion size both inside and outside the home. Simply educating the public about which foods to eat or not to eat is not enough, as an equally important issue is the quantity of food being consumed. While the exact contribution of portion size changes to the in-

Figure 2. Portion Sizes for Selected Food Items Consumed by Eating Location for Americans Aged 2 Years and Older, 1994-1998



Error bars indicate SE.

creases in US overweight and obesity rates cannot be determined, the prevalence of adult obesity has increased from 14.5% in 1971 to 30.9% in 1999.20 The results of this study indicate that control of portion size must be systematically addressed both in general and as it relates to fast food pricing and marketing. The best way to encourage people to eat smaller portions is if food portions served inside and outside the home are smaller. However, this change in behavior may be difficult to achieve due to the US advertising climate and its influence on the public.

Author Contributions: Study concept and design, acquisition of data, critical revision of the manuscript for important intellectual content, obtained funding, and study supervision: Popkin.

Analysis and interpretation of data: Nielsen, Popkin. Drafting of the manuscript, statistical expertise, and administrative, technical, or material support: Nielsen. Funding/Support: This study was funded by grants from the National Institutes of Health (R01-HD30880, R01-HD39183, and R01-HD38700). Funding also came from the University of North Carolina at Chapel Hill.

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Trends in Energy Intake in U.S. between 1977 and 1996: Similar Shifts Seen across Age Groups

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Abstract

NIELSEN, SAMARA JOY, ANNA MARIA SIEGA-RIZ, AND BARRY M. POPKIN. Trends in energy intake in U.S. between 1977 and 1996: similar shifts seen across age groups. *Obes Res.* 2002;10:370–378.

Objective: To determine the trends in locations and food sources of Americans stratified by age group for both total energy and the meal and snack subcomponents.

Research Methods and Procedures: Nationally representative data was taken from the 1977 to 1978 Nationwide Food Consumption Survey and the 1989 to 1991 and 1994 to 1996 (and 1998 for children age 2 through 9) Continuing Surveys of Food Intake by Individuals. The sample consisted of 63,380 individuals, age 2 and up. For each survey year, the percentage of total energy intake from meals and snacks was calculated separately for 2- to 18-year-olds, 19-to 39-year-olds, 40- to 59-year-olds, and those 60 years and older. The percentage of energy intake by location (at-home consumption or preparation, vending, store eaten out, restaurant/fast-food, and school) and by specific food group was computed for all age groups separately.

Results: The trends in location and food sources were almost identical for all age groups. Key dietary behavior shifts included greater away-from-home consumption; large increases in total energy from salty snacks, soft drinks, and pizza; and large decreases in energy from low- and mediumfat milk and medium- and high-fat beef and pork.

Discussion: Total energy intake has increased over the past 20 years, with shifts away from meals to snacks and from at-home to away-from-home consumption. The similarity of changes across all age groups furthers the assertion that

broad-based environmental changes are needed to improve the diets of Americans.

Key words: dietary trends, food sources, locations, fastfood, restaurants, total energy

Introduction

The rapid increase in obesity across all age groups, coupled with reductions in the age when obesity comorbidities emerge, force us to focus on the overall American diet for individuals of all ages (1–3). During this time of rising prevalence in obesity, the levels of physical activity have decreased, and important shifts in diet have occurred (4). Americans have increased their consumption of sugars and energy-dense foods (5). Some of these shifts may be explained by the fact that people are obtaining a greater percentage of their food outside the home, specifically from restaurant and fast-food places (6–9). The largest increases in types of food consumed mirror the shifts in consumption from at home to away from home (10,11). These shifts include increased intakes of salty snacks, soft drinks, and pizza (12,13).

Although there have been many studies that looked at various components of the American diet as well as at selected age groupings, there have been no studies that looked solely at total energy intake or at all age groups in one analysis. Furthermore, we lack information on whether similar shifts across the age groups have occurred. It is important to examine total energy intake because certain scholars feel that there is a continually increasing amount of energy being consumed by Americans over the past 20 years (13,14). We investigated energy intake trends among much of the American population by looking at the ages broken into broad age categories: children 2 to 18 years old, young adults 19 to 39 years old, middle-aged adults 40 to 59 years old, and older adults (hereafter termed elderly) age 60 and up. The use of age-adjusted results allowed us to assess trends explained by changes in eating behavior. This study focuses on the shifts in energy intake related to eating

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location and the concurrent changes in consumption of certain key food items between 1977 and 1996.

Research Methods and Procedures

Survey Design and Sample

This study used data on subjects age 2 years and above from four nationally representative surveys of the U.S. population. Of the 63,380 individuals, 29,695 participated in the 1977 to 1978 (hereafter referred to as 1977) Nationwide Food Consumption Survey (NFCS77), 14,658 participated in the 1989 to 1991 (hereafter referred to as 1989) Continuing Survey of Food Intake by Individuals (CSFII89), and 19,027 participated in the 1994 to 1996 (hereafter referred to as 1996) Continuing Survey of Food Intake by Individuals (CSFII96). This last survey also included a sample of children age 2 to 9 surveyed in 1998. The United States Department of Agriculture (USDA) surveys from 1977 and 1989 contained stratified area probability samples of non-institutionalized U. S. households in the 48 contiguous states and, in 1996, all 50 states. These surveys were self-weighting, multistage, stratified area samples of the U.S. population. Detailed information pertaining to each survey has been previously published (15-17).

The NFCS77 and CSFII89 surveys collected information on 1 day of intake by an in-home, interviewer-administered 24-hour recall and 2 additional days of self-administered 1-day food records. The CSFII96 collected two non-consecutive, interviewer-administered 24-hour recalls by phone ~ 10 days apart.

For each food consumed in all four surveys, the respondent was asked whether this eating occasion was a meal or snack. The respondent was also asked where the food was obtained; if the food was bought in a store, then it was determined whether the food was eaten at home or whether the food was ever brought into the home. This led to the classification of food sources as either from a vending machine, eaten or prepared at home, from a store but not eaten or ever brought into the home (called store eaten out), from a fast-food establishment or restaurant (called restaurant/fast-food), from a school (termed school), or as a gift from someone or any other source. Aside from food that was bought from a store, food from any other source was considered to be from that source, even if brought into the home. For example, if someone ordered pizza from a pizza place or picked up fast-food on the way home and ate it in the home, that food was still considered to be part of the restaurant/fast-food category.

To examine the thousands of foods contributing to energy intake, the University of North Carolina-Chapel Hill foodgrouping system was used. This system aggregates all the foods in the USDA nutrient composition tables into 74 descriptive and nutrient-based subgroups. In addition, selected popular foods such as pizza, hamburger, and french fries were also identified to examine trends in intake of these foods over time. These foods were identified in a previous paper to examine trends in fat intake (18). It should be noted that the individual food entries actually represent a large number of foods and food codes from the food table.

Statistical Analysis

Descriptive statistics were generated for selected sociodemographic variables of interest, weighted and controlled for sample design effects with STATA 7 (Table 1). Significance testing was done on the sociodemographic variables with a z statistic to test the difference between two proportions. The USDA data contained each food item a person consumed, along with the self-reported eating occasion and self-reported place where food was obtained and eaten. Once foods were categorized by eating occasion (snacks vs. non-snack meals), the average energy (in kilocalories) and the percentage of energy contributed by snacks and nonsnacks (meals) was computed for each survey year by age group. Then, for each survey year, the average percentage of energy consumed from selected snack food categories (salty snacks, desserts, candy, soft drinks, fruit drinks, and alcohol) and other selected food groups (pizza, Mexican, etc.) as well as the location (at home, vending, store eaten out, restaurant/fast-food, and school) were determined separately for each age group: 2- to 18-year-olds, 19- to 39year-olds, 40- to 59-year-olds, and those 60 years and older. These results were adjusted by age, sex, education level, ethnicity, region of the country, urban classification, household size, and poverty level (<185% and >350% of national level). To test for statistical differences, SAS 8.1 (SAS Institute, Cary, NC) and SUDAAN 7.5.6 (Research Triangle Institute, Research Triangle Park, NC) software packages were used; this also allowed for weights and control of sample design effects. A value of $p \le 0.01$ was used to denote statistical significance.

In addition, the same age breakdowns for food location and food sources were examined for sex, race, education, and income for meaningful trends. To explore overall trends and the role of age, we also examined the total amount of calories obtained across the population from a specific location or a key food item. The proportion of the population in each age group in 1980 was multiplied by the mean percentage of energy from each of the elements, thereby weighting the total energy for location or food group by the distribution of the population. This allowed us to look at our results and take into account one of the possible biases that would affect our data.

Results

Total Energy Percentages by Location

Between 1977 and 1996, Americans increased the proportion of total energy obtained from restaurants and fastfood establishments and decreased the proportion from

Table 1. Percentages of p	onulation by	sociodemographic	characteristics	1977 to 1996
Table 1. Percentages of b	ooulanon ov	Sociodelliographic	Characteristics,	17// 10 1770

	1977	1989	1994
Sociodemographic characteristics			
Age 2 to 18 years	31.0%*†	26.1%*	26.0%†
Age 13 to 39 years	31.7%*	34.8%*	33.5%
Age 40 to 59 years	22.1%†	22.2%	24.3%†
Age 60+ years	15.2%	16.8%	16.2%
Total (n)	29,695	14,658	19,027
Male	44.0%*†	47.9%*	48.8%†
Non-Hispanic white	80.3%†	77.4%	72.9%†
Non-Hispanic black	12.6%	11.9%	12.5%
Hispanic	5.8%†	8.2%	10.4%†
Other	1.3%*†	2.5%*‡	4.3%†
Poverty level			
<185% of national level	32.1%	28.2%	30.6%
>350% of national level	30.6%*†	41.6%*	39.3%†
Northeast	24.5%*	20.7%*	19.7%
Midwest	26.4%	24.3%	23.5%
South	31.2%	34.6%	34.9%
West	17.9%	20.4%	21.9%
Central cities	30.0%	30.1%	31.5%
Suburban	37.7%*†	47.6%*	47.2%†
Non-metropolitan	32.3%*†	22.3%*	21.3%†
Low education level			
12 years of education or less	70.3%*†	55.5%*	51.6%†
Mean household size	3.9*†	3.4*	3.4†

^{*} Significant difference between 1977 to 1978 and 1989 to 1991.

home. Energy intake from foods eaten at home decreased by between 11.1% and 20.8% for all age groups from 1977 to 1996. Energy intake from restaurant/fast-food increased by between 91.2% and 208% for all age groups. There was little or no change (13.5% to 34.2%) in the amount of energy obtained from the store-eaten-out category (this only accounts for, at most, 7.8% of the total caloric intake).

For Americans, there was a larger increase in absolute energy intake and a much larger relative increase in energy consumed as snacks, rather than meals, over the past 20 years such that snacks represented 17.7% of the average American's energy in 1996 compared with only 11.3% in 1977 (Table 2). Snacks represented a larger portion of the diets of 2- to 18-year-olds than the diets of other age groups (in 1996, >20% of their energy intake, up from 13% in 1977). Although the elderly still snacked the least, with 14.0% of their energy from snacks, they had the largest

jump in snacking, up from 7.7% in 1977. Although energy from meals has been decreasing for all age groups (down about 7.2% for the average American), the elderly had the smallest decrease in energy from meals; meals still constituted 86.1% of their diet.

There were some important age-group differences in location of consumption. The average American increased restaurant/fast-food consumption for meals from 9.6% to 23.5% between 1977 and 1996, and this represents a change between 104% and 255% per age group. Although all age groups have increased their consumption of meals from restaurants/fast-food establishments, the 19- to 39-year-olds have continued to consume the greatest percentage of restaurant/fast-food meals. In 1996, snacks from the store eaten out represented up to 12.2% of all energy from snacks, whereas meals from the store eaten out represented only up to 5.6% of all energy from meals for this age group.

[†] Significant difference between 1977 to 1978 and 1994 to 1996.

[‡] Significant difference between 1989 to 1991 and 1994 to 1996.

Table 2. Trends in energy intake by eating occasion and location (% energy)*

	Total energy			Meals			Snacks		
	1977 to 1978	1989 to 1991	1994 to 1996	1977 to 1978	1989 to 1991	1994 to 1996	1977 to 1978	1989 to 1991	1994 to 1996
Age 2 to 18 years									
Vending	0.3†‡	0.1†§	0.5‡§	0.2†‡	0.1†§	0.31§	1.1†‡	0.5†§	1.3‡§
At home	75.7†‡	71,1†	65.2‡	75.21‡	70.2†§	64.2‡8	79.4†‡	76.4†\$	69.1‡8
Store/out	5.2†‡	1.9†8	4.5‡\$	5.0†‡	1.2†\$	3.2‡§	6.9‡	5.98	9.3‡§
Restaurant/fast-food	4.8+1	14.6†\$	14.8‡§	4.7+±	15.4†§	16.7‡§	5.711	10.4†8	7.9‡§
School	10.9*‡	9.8†	8.7‡	12.1†‡	11.1†	10.2‡	2.4†‡	2.5†\$	3.018
Other	3.1†‡	2.4†\$	6.3‡\$	2.911	2.1†§	5.5‡8	4.3†‡	4.2†\$	9.5‡§
Total	100	100	100	100	100	100	100	100	100
Total energy (kcal)	1840†‡	1778†§	1958‡§	1600†‡	1510†§	1549‡8	240†‡	267†\$	409‡§
Age 19 to 39 years	2010 t	1770.5	1,2047		1010 3	10.1544	- · · · · · ·	3	
Vending	1.1+1	1.04\$	1.218	0.7†	0.5†8	0.6§	4,4‡	3.8§	4.0‡§
At home	72.4‡	68.4§	57.3‡§	73.0†‡	68.3†§	56.8±§	68.1†‡	69.7†\$	59.5‡§
Store/out	7.8†	3.0†\$	6.7\$	7.5†1	2.3†\$	5.6‡8	10.0†‡	7.5†\$	12.2‡§
			•-	14.6†‡	25.7†§	• • •	11.5†‡	12.9†§	15.7‡8
Restaurant/fast-food	14.2†‡	24.0†§	28.1‡8			30.7‡\$	•	•	
School	0.5†‡	0.4†\$	0.6‡\$	0.5†‡ 3.7†‡	0.4†§ 2.8†§	0.6‡\$	0.3‡ 5.8†‡	0.3§ 5.8†\$	0.3‡§ 8.2‡§
Other	4.0†‡	3.2†\$	6.148	3.71‡ 100	100	5.7‡§ 100	100	100	100
Total	100	100	100						
Total energy (keal)	1856†‡	1940†§	2198‡§	1631†‡	1682†§	1811‡§	244†‡	258†§	387‡8
Age 40 to 59 years	0 = 1.1	0.710	0.014	0.214	0.116	0.540	, ()4	2	2.74
Vending	0.5†‡	0.7†§	0.8‡8	0.3†‡	0.4†§	0.5‡8	1.9‡	3	2.7‡
At home	78.1†‡	73.91	66.8‡	78.2†‡	73.5†§	66.1‡§	76.9†‡	76.5†§	70.8‡§
Store/out	7.6†‡	2.5†\$	5.0‡\$	7.5†‡	2.1†§	4.1‡§	9.0‡	5.1§	9.2‡§
Restaurant/fast-food	11.5†‡	19.2†§	21.8‡§	11.8†‡	20.7†§	24.1‡§	8.5‡	9.08	10.1‡8
School	0.2†‡	0.4†	0.4‡	0.2†‡	0.4^{+}	0.4‡	0.2	0.4	0.4
Other	2.1†‡	3.2+§	5.1‡§	2.0†‡	2.8†§	4.8‡§	3.4†‡	5.8†§	6.8‡§
Total	100	100	100	100	100	100	100	100	100
Total energy (kcal)	1747‡	1753§	1954‡§	1572†‡	1534†§	1632‡§	175†‡	219†§	323‡§
Age 60+ years									
Vending	0.1†‡	0.1†§	0.1‡\$	0.0†‡	0.0†§	0.1‡§	0.3†‡	0.6†	0.5‡
At home	88.5†‡	84.2†§	78.7‡§	88.4†‡	84.1†§	78.0‡§	90.1†‡	84.5†\$	83.2‡8
Store/out	3.4†‡	1.21§	2.4‡\$	3.3†‡	1.1†\$	2.2‡§	4.8†‡	2.7†\$	3.9‡§
Restaurant/fast-food	5.3†‡	11.8†§	13.9‡§	5.5†‡	12.5†§	15.3‡8	2.4†‡	5.7†§	5.2‡\$
School	0.5†‡	0.0†§	0.2‡§	0.6†‡	0.0†§	0.2‡§	0.0†‡	0.0†\$	0.1‡\$
Other	2.1†:	2.7†§	4.7‡8	2.1‡	2.2§	4.3‡§	2.3†‡	6.5†§	7.1‡§
Total	100	100	100	100	100	100	100	100	100
Total energy (keal)	1619†	1574†8	1633§	1495†‡	1412†	1406‡	125+#	162†§	228‡§
All Americans age ≥2 years				,					
Vending	0.6‡	0.68	0.8‡§	0.4†‡	0.3+8	0.4‡§	2.3†‡	2.3†§	2.5‡8
At home	76.9†‡	72.6†\$	64.5‡§	77.0†‡	72.3†§	63.8‡8	76.0†‡	74.8†\$	67.4‡
Store/out	6.3†1	2.3†§	5.2‡§	6.1+‡	1.8†§	4.2‡8	8.2†‡	6.0†§	9.8‡
Restaurant/fast-food	9.4†‡	18.7†§	21.3‡§	9.6†‡	20.0†§	23.5‡8	7.9†‡	10.5†8	11.0‡5
School	3.7†1	2.8†	2.61	4.1†‡	3.1†	2.9‡	1.1‡	1.08	1,14
Other	3.04	2.98	5.7‡8	2.8†‡	2.5†8	5.218	4.5†‡	5.4†§	8.2‡
Total	100	100	100	100	100	100	100	100	100
	100	100	100	100					

^{*} Adjusted for age, sex, education level, ethnicity, region, urban classification, household size, and % poverty, $p \leq 0.01$.

[†] Significant difference between 1977 to 1978 and 1989 to 1991.

[‡] Significant difference between 1977 to 1978 and 1994 to 1996.

[§] Significant difference between 1989 to 1991 and 1994 to 1996.

Table 3. Trends in energy intake by meal pattern type and specific food groups*

	Total energy			Meals			Snacks		
	1977 to 1978	1989 to 1991	1994 to 1996	1977 to 1978	1989 to 1991	1994 to 1996	1977 to 1978	1989 to 1991	1994 to 1996
Age 2 to 18 years									
Salty snacks	2.2†‡	3.6†§	5.1‡§	1.4*‡	2.0†§	2.7‡8	7.6†‡	13.0†§	14.218
Desserts	9.8†‡	9.0†§	9.6‡\$	6.5†‡	5.6†	5.6‡	31.2‡	28.6§	24.9‡§
Candy	1.1†‡	1.4†§	2.1‡8	0.3†‡	0.6†\$	0.6‡8	6.0†‡	6.5†8	7.8‡§
Soft drinks	3.0†‡	4.0†§	5.5‡§	2.2†‡	3.3†§	4.7‡8	7.7†‡	7.9†\$	8.3‡§
Fruit drinks	1.8†:	2.1†§	3.1‡§	1.6†‡	1.818	2.8‡§	3.4†‡	3.6†8	4.1‡§
Alcohol	0.11	0.0†\$	0.1§	0.0†‡	0.0†§	0.0‡§	0.4†‡	0.1†§	0.3‡§
French fries	1.7†‡	2.5†§	2.6‡§	1.9†‡	2.8†§	3.018	0.5†‡	0.6†§	0.9‡§
Hamburgers	0.7†‡	0.9†§	0.648	0.8†‡	1.0†§	0.8‡§	0.3‡	0.38	0.2÷§
Cheeseburgers	0.3†‡	1.2†§	1.2‡§	0.3†‡	1.3†§	1.5‡§	0.1†‡	0.6†	0.4
Pizza	1.4†‡	3.2†§	3.4‡§	1.4†‡	3.5†§	3.9+8	1.4‡	1.3§	1.7‡§
Mexican	0.4†‡	1.2†§	1.6‡§	0.4+‡	1.3†§	1.848	0,1†‡	0.4†§	0.9‡8
Low- and medium-fat milk	14.1†‡	12.0†§	9.8‡8	14.2†‡	12.3†\$	10.0‡8	13.5+‡	10.6†§	8.8‡§
Med- and high-fat beef and pork	8.9†‡	4.0†§	3.1‡§	10.0†‡	4.6†§	3.8‡8	1.2†‡	0.6†§	0.6‡§
High-fat lunchmeats and hot dogs	2.9†‡	2.1†§	2.1‡8	3.2†‡	2.4†	2.4‡	1.2†‡	0.8†\$	0.918
Other	51.7†‡	52.6†§	50.118	55.6†‡	57.5†	56.5‡	25.4†‡	25.0†8	26.1‡§
Total	100	100	100	100	100	100	100	100	100
Total energy (kcal)	1840†±	1778†§	1958‡§	1599†‡	1510†§	1549‡§	240†‡	267†§	409‡§
Age 19 to 39 years	*****		*********		,	4-,*			
Salty snacks	1.81‡	3.2†§	4.2‡§	1.3†‡	2.1†§	2.5‡8	5.8†‡	10.0†\$	11.9‡§
Desserts	7.3†‡	6.8†8	7.0‡§	5.1†‡	4.2†§	4.3‡8	23.8†‡	23.6†§	19.7‡§
Candy	0.6†‡	0.9†§	1.3‡§	0.2†‡	0.3†§	0.3‡§	3.2†‡	5.3†§	5.7‡§
Soft drinks	4.1†‡	5.3+8	7.0‡§	3.1†‡	4.3†§	6.2‡§	10.9†‡	11.7†§	10.7‡§
Fruit drinks	1.0†‡	1.1†8	1.8‡§	0.9‡	0.98	1.548	1.8†‡	1.9†§	3.0‡§
Alcohol	2.6†‡	2.7†§	3.6‡§	1.6†‡	1.7†§	2.1‡§	10.0†‡	9.08	10.6‡§
French fries	1.7†‡	2.2†§	2.5‡§	1.9*‡	2.4†\$	2.9‡§	0,4†‡	0.6†§	0.8‡§
Hamburgers	0.94	0.98	1.0‡§	1.0*	1.0‡§	1.1‡8	0.4†	0.2†§	0.2
Cheesburgers	0.4†‡	1.6†§	1.7‡§	0.4†‡	1.7†§	1.9‡§	0.1+‡	0.7†§	0.7‡8
Pizza	1.3†‡	3.6†	3.1‡	1,3†‡	3.9†	3.4‡	1.7+‡	2.0†8	1.6‡§
Mexican	0.3†‡	1,2†§	1.9‡§	0.4†‡	1.3†§	2.1+8	0.1†‡	0.6†\$	0.8‡\$
Low- and medium-fat milk	7.0†±	5.9+8	4.6‡8	6.8†‡	5.7†§	4.348	8.3†‡	6.7†§	5.9‡8
Medium- and high-fat beef and	7.07+	5.7.8	7.048	0,014	-717 1 M	4	0.0 4	0 18	2.748
-	11 74+	5 248	12+8	13.1†‡	6.0†§	5.0‡§	2.0†‡	0.9†§	0.9‡8
pork	11.7**	5.3†§	4.3‡§	·		2.2‡§	1.5†‡	0.9†§	0.948
High-fat lunchmeats and hot dogs	3.1†‡ 56.1†‡	1.9†\$ 57.5†\$	1.9‡§ 54.2‡§	3.4†‡ 59.6†‡	2.1†§ 62.3†§	60.1‡§	30.2‡	25.98	26.7‡§
Other Total	100	100	100	100	100	100	100	100	100
	1855†‡	1940†\$	2198‡§	1631+‡	1682†§	1811‡§	224†‡	258†§	387‡§
Total energy (kcal) Age 40 to 59 years	105514	194019	7130+8	103174	100718	1011148	2271+	25019	20148
	1.4†‡	3.2†§	3.8‡§	1.0†‡	1.9†§	2.2‡§	5.3†‡	12.1†§	11.6‡8
Salty snacks			0.010				0 0 . 1	23.7†§	26.5‡8
Desserts	8.3†‡	7.6†8	8.978	6.21‡	5,3†§ 0,3†§	5.5 <u>7</u> §	3.3†‡	4.5†§	
Candy	0.5†‡	0.8†\$	1.4‡§	0.2†‡	-	0.4‡8	-		6.6‡\$
Soft drinks	1.9†‡	3.3+8	4.0 ⁺ §	1.5†‡	2.7†\$	3.3‡8	5.6†‡	8.1†§	7.7‡8
Fruit drinks	0.6†‡	0.8†§	1.3‡8	0.5†‡ 1.5†‡	0.7†§	1.2‡\$	0.9†‡	1.4†§ 8.5†§	1.7‡8
Alcohol	2.4†‡	2.9†\$	2.9‡§		2.1†§	1.8 ⁺ §	10.1†‡	8.5†§ 0.3†§	8.2‡8
French fries	1.2*‡ 0.5**	1.6†\$	1.6‡§	1.3†‡	1.8†§	1.9‡§	0.1†‡		0.3‡\$
Hamburgers	0.5†‡	0.6†\$	0.7‡§	0.5†‡	0.7†§	0.8‡\$	0.3† 0.0†‡	0.0†\$	0.1§
Cheeseburgers	0.2†‡	1.0*\$	0.7‡§	0.2†‡	1.1†§	0.8‡\$		0.1†\$	0.2‡8
Pizza Maniana	0.5†‡	2.1†8	1.7‡§	0.5†‡	2.2†	1.9‡ 1.4÷\$	0.6†‡	1.14§ 0.1±8	0.5‡8
Mexican	0.2†‡	0.8+8	1.2‡§	0.2†‡	0.9†\$ 4.9‡\$	1.4‡\$	0.0† ‡ 8.4 + +	0.1†§ 7.0±8	0.3‡5
Low- and medium-fat milk	5.4+‡	5.218	4.5‡\$	5.1†‡	4.9†\$	4.3‡\$	8.4†‡	7.0†§	5.5‡§
Medium- and high-fat beef and	10.71	F 510	4 4±11	12.017	2.13.0	5 1 4 4	1 5 4 4	1.04	0.74
pork	12.7†‡	5.5†\$	4.4‡§	13.9†‡	6.1†\$	5.1‡§	1.5†‡	1.0+	0.7*

Table 3. continued.

		Total energy	ý		Meals			Snacks	
	1977 to 1978	1989 to 1991	1994 to 1996	1977 to 1978	1989 to 1991	1994 to 1996	1977 to 1978	1989 to 1 9 91	1994 to 1996
High-fat lunchmeats and hot dogs	3.0†‡	2.2†	2.0‡	3.2†‡	2.4†	2.2‡	1.5†‡	0.8†§	0.9‡§
Other	61.2†‡	62.4†\$	60.9‡§	64.1†‡	66.9+§	67.2‡§	35.1†‡	31.4†§	29.0‡§
Total	100	100	100	100	100	100	100	100	100
Total energy (kcal)	1747 † ‡	1753§	1954‡§	1572†‡	1534†§	1632‡§	175†‡	219†§	323‡8
Age 60 years		17	•	,		,			
Salty snacks	1.3†‡	1.9†\$	2.618	1.0†‡	1.218	1.418	4.9†‡	8.4†§	9.5‡§
Desserts	9.3†‡	8,9†§	10.418	7.5†‡	6.7†§	7.218	30.3†*	28.1†\$	30.5‡§
Candy	0.4†‡	0.6+\$	0.918	0.1‡	0.2§	0.2‡8	3.3+‡	4.3†§	5.318
Soft drinks	0.9†‡	1.6†§	1.818	0.7†‡	1.3†§	1.4‡§	4.1+‡	4.7†\$	4.11\$
Fruit drinks	0.6†‡	0.8†§	1.1‡§	0.5†‡	0.7†§	0.9+8	1.6†‡	1.9†§	2.2‡§
Alcohol	1.5‡	1.6§	1.9‡§	1.0†	0.9†\$	1.2§	6.4†1	7.7†\$	6.1‡§
French fries	0.8‡	0.9§	1.0‡§	0.9*	0.98	1.1‡§	0.1+‡	0.2†§	0.2‡§
Hamburgers	0.2†‡	0.3†\$	0.3‡\$	0,2†‡	0.4†\$	0.4‡8	0.0†‡	0.018	0.0‡§
Cheeseburgers	0.0†‡	0.3†8	0.3‡§	0.0†‡	0.4+8	0.3‡8	0.0†‡	0.0†§	0.1‡§
Pizza	0.2†‡	0.7†§	0.6‡§	0.2†‡	0.7†§	0.6‡8	0.3†‡	0.4†	0.3‡§
Mexican	0.1†‡	0.3†§	0.318	0.1†‡	0.3+\$	0.3‡\$	0.0	0.0	0.1
Low- and medium-fat milk	6.5†‡	6.4†§	5.6‡§	6.2†‡	6.1†§	5.3‡§	10.8†‡	9.4†8	7.418
Medium- and high-fat beef and			T.1			*17			•
pork	10.95‡	4,5†\$	3.9±§	11.7†‡	4.9†\$	4.5±\$	1.2†‡	0.4†\$	0.4‡8
High-fat lunchmeats and hot dogs	2.5†‡	1.9†\$	2.0‡§	2.7†‡	2.1†	2.1:	0.8*	0.58	1.1‡§
Other	64.8†‡	69.3†	67.3	67.2†‡	73.4†§	72.9‡	36.3†‡	33.9†\$	32.7‡§
Total	100	100	100	100	100	100	100	100	100
Total energy (kcal)	1619†	1574†§	1633§	1495†‡	1412†	1406‡	125†‡	162†§	228‡§
All Americans age ≥2 years	10191	127418	10.7.58	145514	1412	14004	12014	10218	220+5
Salty snacks	1.8†1	3.1†\$	4.1‡8	1.2†‡	1.9†§	2.4+8	6.3†‡	11.1+\$	12.3‡8
Desserts	8.6†‡	7.8†8	8.6‡§	6.1†‡	5.2†§	5.3‡8	27,7†‡	25.6†§	23.9‡8
	0.7†‡	1.0†\$	1.5‡§	0.114	0.3†§	0.4‡8	4.2†1	5.418	6.5‡8
Candy Soft drinks	2.8†‡	4.0†8	5.218	2.1†‡	3.248	4.4‡§	8.1†‡	9.0†8	8.6‡8
	•	1.2†§	1.9‡§	1.0†‡	1.1†\$	1.7‡8	2.2†‡	2.3†\$	3.048
Fruit drinks	1.1†‡	1,218			1.11§		6.2†‡	6.1†\$	6.548
Alcohol	1.6†‡		2.3‡§	1.0†‡ 1.6†‡	2.2†§	1.4‡§ 2.4‡§	0.4†‡	0.119	0.5+8
French fries	1.5†‡	1.9†§	2.1‡§			*	0.41	0.2†\$	• • •
Hamburgers	0.7†‡	0.7†\$	0.7‡§	0.7†‡	0.8†§	0.948	•	0.219	0.2‡8
Cheeseburgers	0.3†‡	1.2†§	1.2‡§	0.3†‡	1.3†§ 2.9†	1.3‡8	0.1†‡		0.4‡8
Pizza	1.0†‡	2.7†	2.5‡	1.0*‡		2.8‡	1.3†‡	1.4†\$	1.2‡§
Mexican	0.3†‡	1.0†\$	1.4‡§	0.3†‡	1.1†\$	1.6‡8	0.0†‡	0.4†§	0.6‡8
Low- and medium-fat milk Medium- and high-fat beef and	8.8*‡	7.4†§	6.0‡§	8.6†‡	7.3†§	5.8‡§	10.4†‡	8.2†§	6.9‡§
pork	10.9†‡	4.9†8	4.0‡§	12.1+‡	5.5†§	4.7‡§	1.5†‡	0.8†§	0.7‡\$
High-fat lunchmeats and hot dogs	3.0†‡	2.0†	2.0‡§	3.2†‡	2.2†§	2.2‡§	1.3†‡	0.8†§	0.9‡8
Other	57.0†‡	59.0†§	56.5‡§	60.5†‡	63.8†	62.7‡§	30.0†‡	27.7†§	27.6‡8
Total	100	100	100	100	100	100	100	100	100
Total energy (kcal)	1791‡	17958	1985‡§	1588†‡	1559†§	1634‡§	203++	236†§	351‡§

^{*} Adjusted for age, sex, education level, ethnicity, region, urban classification, household size, and % poverty, $p \le 0.01$.

[†] Significant difference between 1977 to 1978 and 1989 to 1991.

[‡] Significant difference between 1977 to 1978 and 1994 to 1996.

[§] Significant difference between 1989 to 1991 and 1994 to 1996.

Total Energy Percentages by Key Food Groups

Among the foods that we chose to examine, the largest increases were in consumption of salty snacks, soft drinks, and pizza. For 2- to 18-year-olds and 19- to 39-year-olds, the intake of salty snacks and pizza increased between 132% and 143% from 1977 to 1996. Furthermore, for these two age groups, soft drink consumption increased between 70% and 83% in this time period. During this time, 40- to 59-year-olds increased their salty snack intake by 280% and of soft drinks by 110%. The increases for the elderly were very small. Consumption of candy, fruit drinks, french fries, cheeseburgers, and Mexican food also increased for all age groups but only accounted for a small percentage of the total diet, and the changes over time were small. Low- and medium-fat milk and medium- and high-fat beef and pork consumption decreased substantially across all age groups, and high-fat luncheon meat and hot dog intake decreased slightly (Table 3).

For all Americans age 2 years and up, there were some overall differences in energy intake in snacks and meals with respect to key food items. In general, across all age groups for both snacks and meals, consumption of low- and medium-fat milk and desserts decreased. The other food groups with important trends, french fries, hamburgers, cheeseburgers, pizza, Mexican food, and medium- and high-fat beef and pork, were not important components of snacks but rather of meals. Overall, Americans increased their energy intake of french fries, hamburgers, cheeseburgers, pizza, and Mexican food as part of meals from 3.9% to 9% from 1977 to 1996. If one looks at the age patterns for these foods as a meal, 2- to 18- and 19- to 39-year-olds increased their intake from ~5% of energy to 9% to 11% of energy; the increases were much smaller for the other age groupings.

Sugared beverages (combined food group of fruit drinks and soft drinks) increased more for meals overall but played a larger role in snacks. Overall, Americans increased their consumption of sugared beverages as part of a meal from 3.1% to 6.1% and as part of a snack from 10.3% to 11.6%. Furthermore, sugared beverages were consumed more by younger age groups, 2- to 18-year-olds and 19- to 39-year-olds.

For snacks, the largest increases were in the salty snack category; overall, Americans increased their salty snack consumption as a snack from 6.3% to 12.3% over 20 years; however, for meals, these foods only increased from 1.2% to 2.4%. All age groups significantly increased their consumption of this group of foods.

Are there age-related differences in the trends? An important and interesting finding was the fact that although each age group increased its energy intake from certain locations as well as from certain key foods, the increase was

in proportion to that of the other age groups. In Figures 1 and 2, we present the age-adjusted relative shift in the energy consumed by selected food locations and selected food groupings from 1977 to 1996. These results were ageadjusted to the 1980 U.S. census age distribution of persons ≥2 years in the U.S. because of the significant shift in the age distribution of the population between the years of 1977 and 1996. These figures provide a sense of how the proportion of energy for the average American in 1977 changed for each age group in the subsequent 20 years. For instance, 2- to 18-year olds are consuming ~28% of their total energy intake from foods consumed at home, whereas 19- to 39year-olds are consuming ~35%, 40- to 59-year-olds are consuming 21%, and the elderly are consuming 17%. This has remained remarkably constant over the past 20 years as has restaurant/fast-food consumption. For instance, the younger 2- to 18-year-olds consumed 27% and 28% of total at-home energy in 1989 and 1996, respectively. In other words, there was no shift in the relative proportion of energy consumed at home for this age group. It is important to note, however, that the total energy from at-home food increased for this 2- to 18-year-old age group, i.e., the total kilocalories consumed in 1977 and 1996 were 1839 and 1958 kilocalories, respectively. In all cases, the absolute energy changed over time; however, the percentage shifts in types of food and locations were very small.

We can also see that the 2- to 18-year-olds consumed 28% of all energy from the home but only 19% of all energy from restaurant and fast-food sources, whereas the proportions were much greater for the away-from-home category for 19- to 39-year-olds (24% of at-home and 51% of restaurant/fast-food energy; Figure 1).

Interestingly, if there was any shift in the types of foods consumed by the age groupings, there was a small shift away from those aged 2 to 18 toward those aged 19 to 39 with regard to the total proportion of the fast-food grouping of hamburgers, cheeseburgers, french fries, and pizza. Approximately 34% of salty snacks were consumed by 2- to 18-year-olds, and this has remained relatively constant for the past 20 years. This is also true for the other age groups in which another ~38% of salty snack calories were eaten by 19- to 39-year-olds, ~18% by 40- to 59-year-olds, and ~9% for 60-year-olds. This trend is further confirmed with other food categories, including a combined fruit drink and soft drink category and a combined fast-food category that includes hamburgers, cheeseburgers, french fries, and pizza (Figure 2).

In addition, the same age breakdowns for food location and food sources were examined for meaningful trends by sex, race, education, and income. The differences betweengroups were very small and are not reported. The only very substantial difference was that men's intake of alcohol as a snack was much higher than that of women.

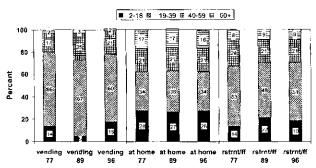


Figure 1: Trends in the proportion of food consumption for selected eating locations by age groups, 1977 to 1996.

Discussion

At a time of increased concern about a positive energy imbalance and the resulting increase in obesity, few studies have focused on trends in total energy intake and its sources. If the trends in total energy intake are to be believed, then Americans have increased their energy consumption over the past 20 years (4,12-14). Although there are many shortfalls in the methods used to collect dietary data and thus the possibility of measurement error exists, there is still much that can be obtained from the data that has been collected. Although there were major methodological differences in the survey methodologies for collecting dietary data for both the National Center for Health Statistics (NCHS) National Health and Nutrition Examination Survey and the USDA's CSFII, there is still some feeling that there has been a real increase in energy intake between 1989 and 1996 (14). This is further supported by the fact that underreporting has increased over time (19). Also there is no information in the U.S. to indicate systematic bias in reporting by eating location. Thus, we feel that the trends in eating behavior highlighted are still representative of those occurring among Americans.

The most significant trend is clearly the continued shift of our energy intake from home to away-from-home sources. Today the average American consumes <65% of his/her energy at home. Over the past 20 years the decline has been from 76.9% of energy consumed at home to 64.5%. The vast amount of this increase has been a more than doubling of the energy consumed at restaurants and fast-food establishments. Some age groups, such as young adults aged 19 to 39, consume close to 30% of their energy from restaurant and fast-food establishments. Older adults and the elderly consume much less. Many other scholars have reported similar shifts toward greater food consumption in restaurants and fast-food places (6-9).

At the same time there have been important changes in the foods consumed. As would be expected from the increase in restaurant and fast-food consumption, important increases have occurred in the proportion of the energy intake from pizza, cheeseburgers, and french fries. The

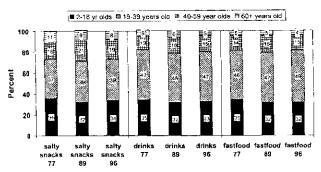


Figure 2: Trends in the proportion of food consumption for selected food groupings by age groups, 1977 to 1996.

largest shifts have been in energy from sugared beverages. The most important relative decreases have been in milk and meat products eaten alone. This reflects the important shift to higher-fat mixed-grain-based dishes (20,21). Another interesting point is that in 1996 all of the hamburgers and cheeseburgers that were consumed and 50% or more of the french fries that were consumed by all age groups were consumed in a restaurant or fast-food establishment. This means that few individuals are preparing at home certain items that can easily be obtained outside the home.

As would be expected when restaurants and fast-food establishments are where people go to get meals, there have also been increases in consumption of french fries, cheeseburgers, hamburgers, pizza, and Mexican food as meal items. Furthermore, it has been shown that for snacks, salty snacks as well as soft drinks are being consumed in greater quantities. In addition, store eaten out is the location that is increasing for snacks. This further confirms the assertion that the changes in food location and the changes in food items are not separate issues but really the same issue. One cannot look at these issues individually without missing part of the story behind why the changes are taking place. To completely understand the changes in the diets of Americans one needs to look at the diet from the perspective of both key foods and food location. This enables us to present the whole picture of how American diets are changing.

Our results contradict the general feeling that the major shifts in eating behavior are among the young. Although most nutritionists and many authors have felt that certain age groups were changing at a faster pace than others, specifically that adolescents and young adults were eating more fast-foods outside the home than middle-aged adults and the elderly, this is not the case (22,23). All age groups are increasing their energy intake from specific locations and for specific food items in proportion to one another. Although there are differences in the amounts of foods consumed and the location of foods consumed by age, these differences have remained constant over the past 20 years. This dispels the idea that certain age groups are increasing

their intake disproportionately (e.g., the explosion in intake of soft drinks or french fries was only for teenagers or other selected subpopulation groups). In other words, it has been shown that intake of foods eaten outside the home is increasing and contributes to increased energy intake and, possibly, the increase in obesity as well (4,24). Indeed, even so-called fast-foods such as burgers, french fries, and pizza are consumed more by the young and the middle-aged, but over time these age groups are still consuming the same proportion of these foods in 1996 as they were in 1977. This similarity of trends across all age groups also dismisses the idea of a cohort effect taking place. This raises a very important issue that our whole environment is changing, not just the actions of certain individuals.

It is apparent that people of all ages are making unhealthy choices both inside and especially outside the home, and this should be the focus of public health policies and interventions. Although there have been some positive changes, including decreased consumption of medium- and high-fat beef and pork, there seem to be many other components of the American diet that need to be changed. One important way of changing people's diets is to encourage them to eat at home more and to make healthier choices when eating out. Consumers need to be encouraged to eat more fruits and vegetables and fewer high-fat mixed-grain-based dishes. It is hoped that if consumers change their diets to include more healthful food choices inside and outside the home, the rise in obesity will be curbed along with the accompanying rise in chronic diseases (9,25).

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RESEARCH AND PRACTICE

Attacking the Obesity Epidemic: The Potential Health Benefits of Providing Nutrition Information in Restaurants

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Sixty-four percent of American adults are either overweight or obese, and the obesity epidemic shows few signs of weakening. 1,2 Although the precise number of deaths attributable to obesity is difficult to estimate, obesity is clearly a major cause of preventable death. 3,4,5 Not surprisingly, improving the healthfulness of the American diet has become a national health priority.^{4,6} The increasing prevalence of obesityrelated diseases has been blamed, in part, on the increased consumption of foods prepared outside the home. Restaurant expenditures have increased consistently in recent decades; consumers now spend more than \$400 billion annually.7

Increased consumption of food prepared outside the home and the rising percentage of overweight Americans have made the failure to disclose the nutritional content of restaurant foods a significant public health issue. Whereas the Nutrition Labeling and Education Act increased the availability of nutrition information on packaged foods, foods purchased for immediate consumption are exempt from nutrition disclosure requirements. Typically, fast-food restaurants make nutrition information available to consumers upon request through brochures or on their corporate Web sites. Most dinner house restaurants (i.e., restaurants that offer table service in an informal atmosphere) disclose the nutrient content of their menu items only via the Internet, if at all.

Laws governing the provision of nutrition information in restaurants have been under consideration by Congress. The Menu Education

Objectives. Requiring restaurants to present nutrition information on menus is under consideration as a potential way to slow the increasing prevalence of obesity. Using a survey methodology, we examined how accurately consumers estimate the nutrient content of typical restaurant meals. Based on these results, we then conducted an experiment to address how the provision of nutrition information on menus influences purchase intentions and reported preferences.

Methods. For both the survey and experiment, data were analyzed using analvsis of variance techniques.

Results. Survey results showed that levels of calories, fat, and saturated fat in less-healthful restaurant items were significantly underestimated by consumers. Actual fat and saturated fat levels were twice consumers' estimates and calories approached 2 times more than what consumers expected. In the subsequent experiment, for items for which levels of calories, fat, and saturated fat substantially exceeded consumers' expectations, the provision of nutrition information had a significant influence on product attitude, purchase intention, and choice.

Conclusions. Most consumers are unaware of the high levels of calories, fat, saturated fat, and sodium found in many menu items. Provision of nutrition information on restaurant menus could potentially have a positive impact on public health by reducing the consumption of less-healthful foods. (Am J Public Health. 2006;96:1669-1675. doi:10.2105/AJPH.2004.054973)

and Labeling Act would require chain restaurants with 20 or more outlets to provide key nutrient information. Legislation has also been proposed in several states (e.g., New York) that would require restaurants with 10 or more national locations to disclose the calorie and nutrient content, such as fat and saturated fat levels, of their foods.8 The Food and Drug Administration has initiated preliminary discussions about national standards for the provision of nutrition information in restaurants in response to these legislative initiatives.9

We examined the potential public health benefits of providing easily accessible nutrition information in restaurants through 2

studies. In study 1, a survey of consumers was used to examine the accuracy of consumers' expectations of the calorie, fat, saturated fat, and sodium levels of restaurant foods, and sought to determine whether the difference between expected and objective levels varied depending on the calorie and nutrient levels of the items. In study 2, drawing on findings from our survey, we investigated how the provision of nutrition information on a menu affected consumers' attitudes and purchase intentions when objective calorie and nutrient levels were either much higher or about the same as consumers expected.

STUDY 1: SURVEY

Recent legal and regulatory initiatives regarding nutrition information disclosure in restaurants are largely driven by an interest in the negative health consequences associated with the overconsumption of calories and nutrients such as fat, saturated fat, and sodium. This raises an important question: What are the expectations of reasonable consumers regarding

the nutrient levels of typical restaurant fare? Study 1 compared estimated calorie, fat, saturated fat, and sodium levels of foods typically served in dinner house restaurants with objective values determined by laboratory testing.

We proposed that most consumers lack the expertise necessary to estimate calorie and nutrient levels accurately. Because nutrition information is difficult, if not impossible, to obtain in most dinner house restaurants, consumers are unlikely to realize that large restaurant portions of higher-calorie and higher-fat menu items (e.g., large bowl of fettuccine Alfredo) may exceed a full day's worth of fat and saturated fat. Therefore, we expected consumers to substantially underestimate calories and fat,

saturated fat, and sodium levels. This is consistent with previous research showing that when presented with large portion sizes of lesshealthful foods, professional nutritionists underestimated calorie levels by between 200 and 600 calories. 10 However, we anticipated that consumers' estimates would be more accurate for the food items lower in calories and fat (e.g., grilled chicken breast).

Thus, we hypothesized that (1) the difference between consumers' expectations and objective levels of calories and nutrients would be greater for items with higher levels of calories, fat, and sodium than for items with lower levels of calories, fat, and sodium (hypothesis 1) and that (2) a greater percentage of consumers would underestimate calorie and nutrient levels for menu items with higher levels of calories, fat, and sodium than for items with lower levels (hypothesis 2).

METHODS

Study participants were recruited through a statewide mail research panel and by undergraduate students. Ninety-seven percent of respondents had dined at a restaurant in the past month; the mean dining-out frequency was 14 meals. Almost all (97%) were high-school graduates and 81% had at least some college. The median age of respondents was 39 years, and 60% were female. The total sample size was 193 respondents. Results of tests of hypotheses were consistent across demographic groups, the household research panel respondents, and the sample of adult consumers.

For 9 restaurant entrées, survey participants were given serving size information and brief item descriptions, similar to information that would appear on a menu. For each item, participants estimated calories, fat, saturated fat, and sodium levels. Measures of the objective (actual) calorie and nutrient levels for each of the 9 items were obtained from independent laboratory testing performed previously for dinner house restaurant items. 11 Three items shown in Table 1 (e.g., grilled chicken breast) were lower in calories and fat (370 to 640 calories; 6 to 26 g of fat) than other entrées. Five items (e.g., hamburger with fries) were much less healthful (930 to 1660 calories; 63 to 97 g of fat). (Although it can be argued that there are no "unhealthful"

TABLE 1—Accuracy of Consumers' Estimates of Calories, Fat, Saturated Fat, and Sodium for Restaurant Menu Items^{a.b}

			Calories				Fat				Sodium			S	Saturated Fat	
			Mean Difference				Mean Difference				Mean Difference		Mean		Mean Difference	
			Between	Percentage			Between	Percent	Mean		Between	Percentage	Saturated	Objective	Between	Percentage
	Mean		Expectations	Underestimating Mean Fat		Objective		Expectations Underestimating	Sodium	Objective	Expectations	Underestimating	Fat	Saturated	Expectations	Underestimating
	Calorie	Calorie Objective		Calories	Expectation	Eat		Fat		Sodium	and Objective	Sodium	Expectation		and Objective	Saturated Fat
	Expectation Calorie Estimates Levels	calorie Levels	Levels (% of Misestimation) ^c	(Overestimating Calories)	Estimates, g	Levels, g	Levels (% of (Misestimation)	(Overestimating Fat)	Estimates, mg	Levels, mg	Levels (% of Misestimation) ^d	(Overestimating Sodium)	Estimates, g	Levels, g	Levels (% of Misestimation)	(Overestimating Saturated Fat)
Less-healthful items																
Means	694	1336	-642 (-93)	90 (10)	32	92	-44 (-137)	90 (10)	457	2014	-1557 (-341)	93 (7)	15	30	-15 (-100)	80 (20)
Fettuccine Alfredo	704	1500	-796 (-113)	90 (10)	31	26	-66 (-213)	96 (4)	478	1030	-552 (-115)	88 (12)	13	48	-35 (-269)	95 (5)
Hamburger and fries	777	1240	-463 (-60)	88 (12)	37	29	-30 (-81)	85 (15)	523	1270	-747 (-143)	87 (13)	17	29	-12 (-71)	77 (23)
Chicken fajitas	704	1660	-956 (-136)	96 (4)	31	63	-32 (-103)	82 (18)	451	3660	-3209 (-712)	99 (1)	14	19	-5 (-36)	67 (33)
Chef's salad	452	930	-478 (-106)	90 (10)	21	71	-50 (-238)	97 (3)	328	2510	-2182 (-665)	99 (1)	6	18	-9 (-100)	82 (18)
Patty melt and fries	834	1350	-516 (-62)	84 (16)	41	81	-40 (-98)	88 (12)	504	1600	-1096 (-217)	93 (7)	20	37	-17 (-85)	80 (20)
More-healthful items																
Means	200	543	-43 (-9)	73 (27)	23	15	8 (35)	37 (63)	333	1180	-847 (-254)	92 (8)	11	9	5 (45)	30 (70)
Chicken breast	479	640	-161 (-34)	78 (22)	22	14	8 (36)	37 (63)	321	820	-499 (-155)	88 (12)	10	2	2 (20)	27 (73)
Pot roast	699	620	43 (6)	65 (32)	33	26	7 (21)	48 (52)	425	1310	-885 (-208)	92 (8)	15	11	4 (27)	47 (53)
Turkey sandwich	358	370	-12 (-3)	75 (25)	15	9	(09) 6	26 (74)	254	1410	-1156 (-455)	96 (4)	7	2	5 (71)	17 (83)
Very unhealthful item: cheese	869	3010	-2141 (-246)	99 (1)	40	217	-177 (-443)	97 (3)	537	4890	-4353 (-811)	99 (1)	21	91	-70 (-333)	93 (7)
fries with ranch dressing																

Information provided for the 9 restaurant menu items included brief descriptions, size of the item in ounces, and any side dishes, all drawn from Jacobson and Hurley.¹¹ On the basis of a 2000-calorie diet, the recommended daily values are 65 g for fat, 2400 mg for sodium, and 20 g for saturated fat.

This is the difference between consumers' calorie estimates and the objective levels determined by laboratory testing. The percentage (shown in parentheses) is the mean difference divided by consumers' sodium estimates and the objective levels determined by laboratory testing. The percentage (shown in parentheses) is the mean difference divided by consumers' sodium estimates and the objective levels determined by laboratory testing. The percentage (shown in parentheses) is the mean difference divided by consumers' expectations (e.g., -1557/457 = -341%).

foods within the context of an entire diet, for the sake of brevity, we use the terms "less" and "more healthful" to refer to menu items higher/lower in calories, fat, and sodium.) The remaining item (cheese fries with ranch dressing) had extremely high calorie and nutrient levels (3010 calories; 217 g of fat) and was termed "extremely unhealthful."

RESULTS

For each menu item, Table 1 presents consumers' estimated (expected) calorie and nutrient levels, the objective levels, the mean difference between estimated and objective levels, and the percentage of consumers who either overestimated or underestimated calorie and nutrient levels. As shown, less-healthful items were judged to be higher in calories and fat than more-healthful items. This indicates that consumers are at least somewhat aware of nutritional differences among foods.

To test hypothesis 1, individual accuracy scores for calorie and nutrient levels were calculated by subtracting the objective levels from the consumer-estimated levels. These deviation scores were used as the dependent variables in a series of repeated-measures analyses of variance. Differences between consumers' estimates and objective values varied substantially across the morehealthful, less-healthful, and extremely unhealthful items.

For calories, results of the repeatedmeasures analyses were highly significant (F=2530; P<.001). On average, participants underestimated the calorie levels of lesshealthful items by 642 calories; objective levels (1336 calories) were almost twice as high as consumers' estimates. The calorie content of cheese fries with ranch dressing (3010 calories) was underestimated by more than 2000 calories. Consumers slightly underestimated calories of the more-healthful items. Follow-up contrasts on the difference scores between expected and the objective calorie measures showed significant differences between the more-(M=-43) and less-(M=-642) healthful items, as well as between the less-healthful items and the extremely unhealthful item (t values=37.4 and 54.8, respectively; P<.001 for both comparisons). Thus, as posited, the differences between consumers' calorie estimates and objective levels were far greater for items with less-healthful nutritional content.

Similarly, consumers' expectations of nutrient levels (fat, saturated fat, and sodium) were less consistent with the objective levels for less-healthful items than for more-healthful items. Results from repeated-measures analyses of variance for each nutrient using the difference between consumers' estimates and objective values as the dependent variable resulted in significant findings for all 3 nutrients (F values exceeded 700 for all tests, P < .001). For the less-healthful items, consumers underestimated fat and saturated fat levels by 44 g and 15 g, respectively—amounts that were more than 60% of the recommended daily values. Estimated fat and saturated fat levels for the more-healthful items were more consistent with objective levels (and even slightly higher). Consumers underestimated sodium levels for the more-healthful items by 847 mg, whereas they underestimated the amount of sodium in the less-healthful and extremely unhealthful items by 1557 mg and 4353 mg, respectively. For all nutrients, follow-up contrasts showed significant differences between the more-/less-healthful and less-/extremely unhealthful groups.

To address differences in percentages of consumers underestimating calorie and nutrient levels, cross-tabulation analyses were performed. As shown in Table 1, 90%, 99%, and 73% of respondents underestimated calories for the less-healthful, very unhealthful, and more-healthful items, respectively $(\chi^2 = 102.2; P < .001)$. For fat, 90%, 97%, and 37% of respondents underestimated levels for the less-healthful, very unhealthful, and more-healthful items, respectively (χ^2 = 509.1; P<.001). The pattern of findings was similar for saturated fat (χ^2 =433.6; P<.001). Although most consumers underestimated sodium levels of all the items, differences were significant ($\chi^2 = 13.3$; P < .01). These findings support hypothesis 2.

STUDY 2: EXPERIMENT

Given that consumers appear unaware of the high levels of calories, fat, and sodium found in many foods typically served in restaurants, the purpose of study 2 was to examine the potential public health benefits associated with the provision of nutrition information in restaurants. Specifically, we examined how providing nutrition information influenced consumers' attitudes and purchase intentions for restaurant menu items. For each menu entrée, consumers were also asked to estimate how likely they were to gain weight and develop heart disease if that food item was included as a regular part of their diet. These risk perceptions were expected to be influenced by the provision of nutrition information.

Classic expectancy disconfirmation theory can be used to predict consumers' responses when accurate calorie and nutrient information are disclosed. 12,13 According to this theory, consumers form initial expectations about specific product attributes. If the actual information or subsequent experience does not meet expectations, then attribute dissatisfaction will occur, which creates negative attitudes. 12 If actual product information exceeds expectations, positive attitudes result.

Study 1 showed that calories, fat, and sodium in less-healthful restaurant menu items are much higher than consumers expect. However, the objective nutrient levels of morehealthful items were relatively consistent or slightly better than what consumers expected. Therefore, for less-healthful items, the provision of nutrition information should disconfirm consumers' nutrition-related expectations resulting

in unfavorable attitudes and decreased purchase likelihoods. Consumers' perceptions regarding the likelihood of weight gain and heart disease risk should also be higher. 14 Expectancy disconfirmation theory thus suggests that the discrepancy between expected and objective nutrient levels should result in an interaction between the provision of nutrition information and the healthfulness of the menu item. Negative disconfirmation for less-healthful items is expected to lead to decreases in measures of attitudes and purchase intentions and to increase choice preference for more-healthful items. In addition, these effects should generally be greater when both the number of calories and the nutrient levels are provided, compared with when calorie information (a single attribute) is presented alone.

Thus, we hypothesized that (1) when objective nutrition information is less favorable than consumers expect, providing nutrition information would have a greater negative influence on product attitudes and purchase intentions and a greater positive influence on perceived likelihood of weight gain and heart disease (hypothesis 3a); (2) when objective nutrition information is less favorable than consumers expect, providing both calorie and nutrient information would have the strongest influence (hypothesis 3b); and (3) providing nutrition information on menus would decrease choice preference for items with objective nutrition information that is less favorable than consumers expect and increase choice preference for items more consistent with expectations (hypothesis 4).

METHODS

Participants

Participants in a geographically dispersed area throughout a single south-central state responded to a mail survey. Participants were mailed packets that included 1 of the randomly assigned 6 menu stimuli, a survey including measures of interest, and a stamped self-return envelope. Completed surveys were returned by 241 respondents, a response rate of 50%. Almost all respondents were highschool graduates (97%), 63% were female, and ages ranged from 23 to 85 years. For the 6 groups in the design, cell sizes ranged from 38 to 42 participants.

Design

Study 2 had a 3 (nutrition information)×2 (daily value information)×4 (menu item) mixed experimental design. The nutrition information and daily value manipulations are between-subjects factors and menu item is a repeated-measure factor. Nutrient information conditions are: (1) calories, fat, saturated/ trans fats, and sodium levels presented, (2) only calorie information presented, and (3) no nutrition information presented (status quo in most restaurants). (Note that most proposed legislation would require calorie-plus-nutrient information for restaurants that use menus, but only calorie information for fast-food restaurants with menu boards.) The daily value information disclosure is (1) daily value

TABLE 2—Means (SD) for Purchase Intentions and Product Evaluation-Dependent Variables for Nutrition Information-Provision Conditions

		onsistent With expectations	Items More Consistent With Nutrition Expectations		
Dependent Measures for Nutrition Information–Provision Conditions	Chef's Salad	Hamburger and French Fries	Grilled Chicken Breast and Baked Potato	Turkey Sandwich	
Product attitude					
No nutrition information	5.37 (1.8)	4.46 (1.8)	5.66 (1.4)	5.25 (1.6	
Calories only	5.18 (1.6)	4.16 (1.9)	5.80 (1.3)	6.02 (1.4	
Calories and nutrients	4.38 (1.9)	3.72 (2.0)	5.52 (1.5)	5.64 (1.5	
Purchase intentions					
No nutrition information	4.92 (1.7)	4.44 (2.1)	5.59 (1.6)	4.86 (1.9	
Calories only	4.68 (1.7)	3.80 (2.1)	5.58 (1.6)	5.86 (1.5	
Calories and nutrients	3.97 (2.0)	3.43 (2.1)	5.55 (1.7)	5.48 (1.7	
Perceived likelihood of weight gain					
No nutrition information	3.89 (2.0)	7.24 (1.9)	4.32 (1.9)	3.75 (2.0	
Calories only	4.71 (2.3)	7.80 (1.8)	4.43 (1.8)	2.97 (1.7	
Calories and nutrients	5.42 (2.3)	7.53 (1.8)	4.80 (1.7)	3.72 (1.8	
Perceived likelihood of heart disease					
No nutrition information	4.05 (1.8)	7.17 (1.6)	3.97 (1.7)	3.92 (1.9	
Calories only	4.59 (2.1)	7.62 (1.6)	3.86 (1.8)	3.10 (2.0	
Calories and nutrients	5.42 (2.1)	7.41 (1.5)	4.23 (1.6)	3.70 (1.9	

recommendations for fat (65 g), saturated fat (20 g), and sodium (2400 mg) based on a 2000-calorie diet, and (2) a control condition without daily values. 15,16 The nutrition information presented was based on laboratory tests of actual restaurant items. The provision of daily value information had no influence on the dependent measures and is therefore excluded from further discussion.

Four of the items included on the menu were deluxe hamburger with fries, chef's salad, chicken breast with baked potato, and turkey sandwich. As shown in Table 1, for the first 2 items, objective levels of calories, fat, and saturated fat exceeded consumers' expectations. For the latter 2, consumers' expectations were more consistent with objective levels. All information and manipulations were

TABLE 3-Effects on Purchase Intention and Product Evaluation-Dependent Variables

	MANOVA	Results		Univa	riate F Values	
	Wilks λ	F	Product Attitude	Purchase Likelihood	Weight Gain Perceptions	Heart Disease Perceptions
Nutrition information	0.93	1.9	4.2*	2.9	4.2*	3.5*
Daily value information	0.98	1.2	2.9	0.9	0.0	0.7
Item type	0.40	60.0**	56.6**	47.9**	218.4**	231.8**
Nutrition information × Item type	0.91	2.5**	4.0**	5.2**	4.8**	4.6**
Nutrition information \times Daily value information	0.94	1.8	2.2	1.4	0.4	0.1
Daily value information×Item type	0.98	1.1	1.4	2.4	0.3	1.2
Nutrition information × Item type × Daily value information	0.97	0.9	2.0	1.1	0.9	0.9

Note: MANOVA = multivariate analysis of variance.

*P<.05; **P<.01.

presented on a 4-color mock restaurant menu stimulus. Respondents were instructed to answer questions regarding the menu items; nutrition was not mentioned.

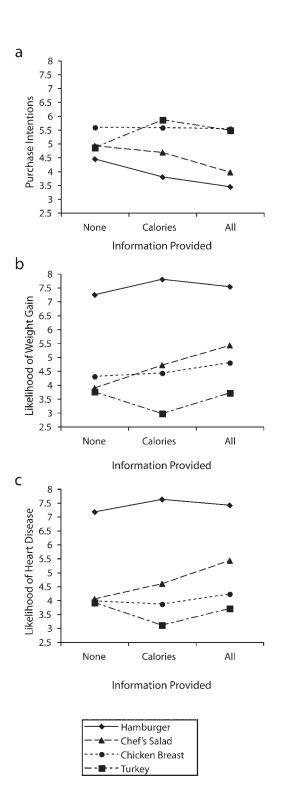
Measures

For each menu item, overall attitude toward the product and purchase intention were assessed using multi-item 7-point scales (all coefficient α's greater than 0.90). To assess consumers' risk perceptions (likelihood of weight gain and heart disease perceptions), 9-point, single-item measures drawn from previous research were employed. 14,17 (Specific items used for measures are available as a data supplement to the online article.) Items were recoded so that higher values indicated more-favorable attitudes and higher perceived risk. A single measure of choice among the 4 items was used ("If you had to choose one of the products described on the mock menu, which one product would you select?").

RESULTS

To test predictions, a doubly multivariate analysis was performed with SPSS 11.5 general linear models (SPSS Inc, Chicago, Ill). Dependent variable means are shown in Table 2 and multivariate and univariate results are shown in Table 3. There are main effects of nutrition information provision and menu item type for the dependent variables as hypothesized and a multivariate interaction between information provision and menu item (P < .01). Univariate interactions are significant for each of the 4 dependent variables. Plots of means relevant to interactions are shown in Figure 1. For the items inconsistent with nutrition expectations (hamburger and chef's salad), purchase intention means followed the predicted pattern. For the hamburger platter, follow-up contrasts showed that relative to the control (M=4.44), there were significant decreases in purchase intentions for both the calories-plus-nutrients (M=3.43; t=-2.93; P < .01) and calories-only (M = 3.80; t = -1.89; P < .05; 1-tailed test) conditions. The difference between the calorie-only and calorieplus-nutrients conditions was not significant.

For the chef's salad, contrasts show that compared with the no-information control condition (M=4.92), there was not a significant



Note. For the hamburger platter and chef's salad, consumers' calorie and nutrient expectations (assessed in study 1) generally were less consistent with objective levels than were the chicken breast dinner and turkey sandwich items.

FIGURE 1-Interaction between nutrition information provided and menu food item for purchase intentions (a), weight gain (b), and heart disease (c).

decrease in purchase intentions from the addition of calorie information (M=4.68). However, purchase intentions for the calories-plusnutrient information condition (M=3.97) were significantly lower than both the control (t=-3.18; P < .01) and the calorie-only (t = -2.41; P < .02) conditions. This pattern is consistent with the nutritional composition of the chef's salad; it contains a moderate number of calories, but substantially exceeds the levels of fat and saturated fat expected by consumers. Thus, hypotheses 3a and 3b were supported.

With the provision of nutrition information, purchase intentions for the expectationconsistent items showed no effect in 1 case and a positive effect in the other case. Specifically, the purchase intentions means were flat for the chicken dinner (ranging between 5.55 and 5.59). For the turkey sandwich, relative to the control (M=4.86), the addition of calorie information (M=5.86; t=3.68; P < .01) and calorie-plus-nutrient information (M=5.48; t=2.22; P<.05) resulted in stronger purchase intentions.

Plots for the perceived likelihood of gaining weight and developing heart disease are shown in Figure 1b and 1c. For both variables, univariate analyses of variance were significant for the chef's salad (P < .01) and turkey sandwich (P < .05), but not significant for the hamburger platter or chicken dinner (P > .15). For the chef's salad, the caloriesplus-nutrients condition led to higher perceived likelihoods of heart disease and weight gain, relative to the calories-only condition (t=2.52 and 1.87, respectively; P < .05). Forthe turkey sandwich, calories alone decreased both perceived likelihoods (P < .05), but the full information did not differ relative to the control. (Presumably, the higher sodium levels revealed in the full-information condition counterbalanced the positive effects of a lower-than-anticipated calorie level.) The pattern of means is particularly interesting for heart disease. With no information, the means for all items except the hamburger platter were almost identical but the calorie and nutrient information widened perceived

differences among these items, and the chef's salad mean increased significantly (P < .01). These findings also supported Hypotheses 3a and 3b.

Consumers' item choices were examined across the 3 levels of nutrition information. Results were significant ($\chi^2 = 15.6$; df = 6; P < .02). When calorie-plus-nutrient information was presented, the percentage of consumers choosing the turkey sandwich (which generally met or exceeded nutrition expectations) increased from 11% to 21%, and it decreased selection of items with higher levels of calories and fat than expected. The share of the chicken dinner (i.e., nutrient levels consistent with expectations) remained constant. In tests comparing the 2 items with higher calories and fat (i.e., items less consistent with expectations) to the 2 morehealthful items, selection of the highercalorie, higher-fat items decreased from 37% to 24% (P < .05) when calorie and nutrition information were provided. These findings supported hypothesis 4.

DISCUSSION

As a response to the increased prevalence of overweight and obesity, which has been linked with the greater consumption of foods prepared outside the home, 18 legislation has been proposed at both federal and state levels that would require the provision of nutrition information for restaurant food items. Study 1 results showed that, for a number of items, consumers vastly underestimated calories, fat, saturated fat, and sodium levels. On average, less-healthful items were underestimated by more than 600 calories and between one third to a full day's worth of the recommended values for fat and saturated fat. If diners consumed 600 more calories than they realized for just 1 restaurant meal per week, an extra 30 000 calories a year would be added to their diets. These unaccounted calories could cause a weight gain of approximately 9 pounds annually, holding all other factors constant. Over several years' time, this degree of misestimation could cause significant weight gain. Given substantial differences between expected and objective values,

these findings indicate that inclusion of nutrition information on menus offers informational benefits to consumers.

Study 2 findings showed that the addition of calorie and nutrient information for dinner house items influenced attitudes, intentions, and choices. Purchase intention and choice decreased for less-healthful items that were worse than expected (hamburger platter and chef's salad), whereas they remained constant or increased slightly for items more consistent with expectations. The largest changes occurred for the chef's salad, which had the largest deviations from consumer expectations. In the absence of nutrition information, the turkey, chicken, and chef's salad items were indistinguishable in terms of the perceived likelihood of heart disease. However, when calorie and nutrient information were provided, there was a larger difference in disease-risk perceptions.

Our findings have significant public health implications and provide support to the notion that new restaurant-oriented nutrition information initiatives may be warranted. However, circumstances unique to the restaurant industry, such as customized orders and

portion size differences, will make provision of exact nutrition information for every single meal and every consumer difficult. Legislation would probably need to apply to items "as offered for sale," and nutrition disclosure would not include customized orders or daily specials.

Because our results showed that consumers substantially underestimated calorie levels for less-healthful dinner house items and that preference for the less-healthful items diminished when nutrition information was disclosed, provision of nutrition information for chain restaurants' standard menu items would appear helpful. We also recognize that further research may identify additional nutrition formats that may be equally or more effective at conveying nutrition information, and that combining possible social marketing initiatives with future nutrition disclosure research seems warranted. In sum, these findings suggest that the provision of easily accessible nutrition information in restaurants may provide significant public health benefits by making it easier for consumers to make more healthful food choices.

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Contributors

S. Burton and E.H. Creyer originated the design of the studies and formulated the hypotheses. S. Burton wrote the first draft of the article and performed initial analyses. J. Kees and K. Huggins worked on data analyses and data collection. All authors participated in critical review and revision of the article based on reviewers' recommendations.

Human Participant Protection

This study was approved by the institutional review board of the University of Arkansas. Informed consent was obtained from study participants.

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Race and Research Perspectives on Minority Participation in Health Studies

Edited by Bettina Beech, DrPH, MPH, and Maurine Goodman, MA, MPH

Race and Research: Perspectives on Minority Participation in Health Studies is a teaching text and resource guide for students, health professionals, public health researchers, and the general public that extends the discussion of environmental factors that influence ethnic minority participation in health studies. This book examines the lack of minority participation in health studies from social, historical, and scientific perspectives.

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The Keystone Forum on **Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity**

Final Report May 2006



Contents

Executive Summary	. 4
Introduction	14
The Forum Process	
The Forum's Purpose, Objectives, and Context of Inquiry	
The Scope of the Discussions	
Key Concepts: Calorie Density and Nutrient Density	
Considerations in Developing Recommendations	
Funding the Recommended Actions	
Chapter 1: Setting the Stage	22
Key Themes	
The Changing Environmental Context	23
The Relationship of Away-From-Home Foods to Body Weight	26
Chapter 2: Understanding and Influencing Consumer Behavior	
What Is Known about Consumer Behavior and Away-From-Home Foods	
Existing Education and Marketing Efforts	
Existing Data-Collection Efforts	
The Forum's Recommendations	46
Chapter 3: Increasing the Availability of Lower-Calorie Products,	
Menu Items, and Meals	
Overview of the Issues	
Menu Design and Cooking Techniques	
Portion Size, Plate Composition, and Menu Pairing	
Beverages	58
The Forum's Recommendations and "Operational Tips"	59
Chapter 4: Providing Consumers with Nutrition Information	
Introduction to the Issue	
Potential Rationales for Providing Nutrition Information for Away-From-Home Foods	
Considerations for the Away-From-Home Sector	
Consumer Use of Nutrition Information	
The Role of Government in Providing Nutrition Information	
The Forum's Recommendations	76
Appendix A: Keystone Forum Supporting Participants, Information Resources,	05
and Project Staff	03
Appendix B: Research Regarding the Association of Away-From-Home Foods and Body Weight	89

02/15/2008	Page 3 of 13

Appendix C: Success Factors in Consumer Acceptance of	
Low-Calorie Innovations in the Away-From-Home Food Market	93
Appendix D: Selected Social Marketing and Education Efforts Relevant to	
Consumer Behavior and Obesity Prevention	101
Appendix E: Summary of Key Government Efforts to Collect Data on	
Consumer Behavior and Away-From-Home Foods	107
Appendix F: The Design and Focus of Needed Consumer Research	112
Appendix G: Summary of Survey Results	115
Appendix H: Summary of National Polls Regarding Consumer Interest	
in Nutrition Information for Away-From-Home Foods	121
Appendix I: Review of Selected Studies: The Impact of Nutrition	
Information on Menu Item Selection	122
Appendix J: Approaches to Providing Nutrition Information	128
Appendix K: Key Abbreviations	134

Executive Summary

Over the past two decades in the United States, obesity has become a public health crisis of epidemic proportions. At present, approximately 64% of all U.S. adults are overweight, including 30% who are obese. Overweight and obesity are associated with increased morbidity and mortality, and also exact significant economic costs. The medical expenses attributable to overweight and obesity are estimated to have reached as high as \$92.6 billion per year—roughly 9.1% of total U.S. medical expenditures.

A number of efforts to address and reverse this public health crisis have been and are being undertaken in the public, private, and nonprofit sectors. This report is the final work product of one such effort—the Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity.

The Keystone Forum was requested and funded by the U.S. Food and Drug Administration.² The Forum brought together a wide diversity of participants to develop joint recommendations for action. The participants included representatives from industry, government agencies, civicsector organizations, and academia. (A complete list of participants can be found in Appendix A of the report.)

The Forum Process

The Keystone Forum on Away-From-Home Foods commenced in December 2004 with a smallgroup planning meeting. Three full-group plenary sessions were subsequently held in Washington, DC, in 2005, and numerous work group discussions were held between plenary meetings. The Forum was convened and facilitated by The Keystone Center, a nonprofit public policy and dispute resolution organization with offices in Colorado and Washington, DC. The Consensus Building Institute provided additional facilitation expertise, and Larmer Consulting assisted with the compilation and editing of this report.³

Keystone Forum participants agreed throughout the process to abide by a set of "operating protocols," which outlined objectives, roles, responsibilities, and a number of discussion principles. Participants were asked to represent their personal views in the discussions and were understood to be speaking on behalf of themselves, not on behalf of their organizations or constituencies. By including their names in Appendix A, Forum participants are indicating that they "generally support" the recommendations and overall content of this report, though they may find some sections more acceptable and compelling than others.

¹ E.A. Finkelstein, I.C. Fiebelkorn, and G. Wang, "National Medical Spending Attributable to Overweight and Obesity: How Much, and Who's Paying?" Health Affairs W3 (2003): 219-226. See www.cdc.gov/nccdphp/ dnpa/obesity/economic consequences.htm.

² The content of this publication does not necessarily reflect the views or policies of the U.S. Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.

³ See www.keystone.org, www.cbuilding.org, and www.larmerconsulting.com.

Forum participants organized the final report, and also this executive summary, into three sections corresponding to the Forum's three primary topics of discussion: (1) Understanding and influencing consumer behavior with regard to away-from-home foods; (2) increasing the availability of lower-calorie products, menu items, and meals at establishments that provide away-from-home foods; and (3) providing consumers with nutrition information regarding awayfrom-home foods.

The Forum's Purpose, Scope, and Rationale

The purpose of the Keystone Forum on Away-From-Home Foods was to consider what can be done, given what is currently known, to support consumers' ability to manage calorie intake with respect to preventing undue weight gain and obesity, within the scope of away-from-home foods. Forum participants hope that the American public will be the ultimate beneficiary of the Forum's work. Toward that end, participants expect that this report will be useful to foodservice operators and their suppliers, policymakers, public health and medical professionals, culinary professionals, patient and consumer advocates, and research scientists.

The Forum's discussions focused on obesity and away-from-home foods. The term *obesity* was used to refer to overweight and obesity together. Similarly, the term foods was frequently used to refer to both foods and beverages. Away-from-home foods include full meals and single readyto-eat items (including take-away foods) purchased at restaurants, prepared-food counters at grocery stores, institutional foodservice settings, and other outlets.

The concepts of calorie density and nutrient density were important parts of the Forum's approach to caloric intake in the area of away-from-home foods. Calorie density (also known as energy density) refers to the amount of calories (i.e., energy) contained in a unit of food (measured by weight, e.g., kcal/g). Nutrient density refers to the amount and availability of nutrients in a unit of food. The Forum focused on assisting consumers with managing appropriate caloric intake pursuant to obesity prevention. However, while appropriate caloric intake is essential to addressing the problem of obesity, it is also important for consumers to get the most nutritional value from their calories.

⁴ The National Institutes of Health define "overweight" in adults as a body mass index (BMI) of 25.0 to 29.9 and "obesity" as a BMI of 30.0 or higher. BMI is defined as the ratio of a person's bodyweight in kilograms divided by the square of his or her height in meters. See www.nhlbi.nih.gov/health/public/heart/obesity/lose wt/ risk.htm#limitations.

⁵ The topic of school meals was not included in the scope of the Forum's discussions. Although foods sold in schools are a significant source of calories for school-aged children, there was a need to limit the scope of the dialogue to a manageable area of inquiry consistent with the U.S. Food and Drug Administration's own core capabilities and activities.

⁶ See www.health.gov/dietaryguidelines/dga2005/report/HTML/G1 Glossary.htm. Less calorie-dense foods are generally those with a higher water content, such as fruits, vegetables, and soups. While energy density and calorie density can be used interchangeably, this report generally uses the latter term.

⁷ See www.diet-and-health.net/glossary.html. Nutrient-dense foods provide substantial amounts of vitamins and minerals, and relatively fewer calories. For an extensive review of literature on nutrient density, see A. Drewnowski, "Concept of a Nutritious Food: Toward a Nutrient Density Score," American Journal of Clinical Nutrition 82, no. 4 (2005): 721-732.

The report does not focus on any particular subgroup of the U.S. population. However, participants acknowledged the unique concerns relating to children, since that population group faces significant long-term health consequences due to the obesity epidemic. Therefore, some of the recommendations include consideration of children's unique needs.

Forum participants agreed to consider the role of food in the context of what is known about obesity—in other words, in light of the fact that food, wherever consumed, is a major factor but not the only factor affecting the incidence of obesity. Because obesity and undue weight gain result from sustained energy imbalance (i.e., caloric intake exceeding caloric expenditure), physical activity is also an essential element in obesity prevention and treatment. While this inquiry focused on food choice and consumption, Forum participants recognized that the broad societal effort to reduce obesity incidence must consider both sides of the energy balance equation.

As of this decade, Americans are eating away-from-home foods more frequently and consuming more calories from away-from-home establishments than ever before. Thus, a wider range of less-calorie-dense, more-nutrient-dense food and beverage choices in away-from-home food outlets, coupled with consumer education and information (especially about energy balance), can help Americans to manage their weight more effectively.

While several recent studies have explored various contributors to obesity, as yet there does not exist a conclusive body of evidence establishing a causal link between the availability or consumption of away-from-home foods and obesity. Preliminary research indicates, however, that the consumption of away-from-home foods can be a factor in determining calorie consumption and body weight, and an important one for many individuals. Participants did not seek resolution on this question, but rather focused on proposing implementable solutions to the challenge of obesity.

The Forum's Recommendations

A summary of Forum participants' recommendations follows. Please note that Chapter 1 does not contain recommendations and so is not summarized below. It describes key observations and background regarding changes in the food environment over the past three decades, and it provides an overview of the research base regarding the relationship between away-from-home foods and body weight. Chapters 2 through 4 also include extensive background information, not summarized here, that provides context for the recommendations and suggested implementation steps.

Chapter 2: Understanding and Influencing Consumer Behavior

To reverse the increase in obesity and undue weight gain in the United States, Forum participants believe the current consumer preference for large quantities of calorie-dense foods should shift to an emphasis on intake appropriate to an individual's needs and to increased consumption of

foods lower in calorie density. However, it can be difficult to change consumers' day-to-day food and activity behaviors, despite the potential longer-term consequences of those behaviors. Thus, messages and education programs directed at consumers should be carefully crafted; they must impart the knowledge and skills consumers need, and they must reach and motivate consumers successfully. Also, strategies should be tailored as needed to specific demographic and cultural audiences.

Much of the existing data and information about consumer eating behavior and attitudes is either not specific to away-from-home foods, not sufficiently timely, or not publicly available. Thus, a research agenda is also needed to augment the publicly available knowledge base and inform the continual development of consumer education programs. It must be stressed, however, that while the knowledge base needs to be improved, enough is known to recommend many important actions. Forum participants believe that reasonable strategies to assist consumers with healthy energy intake should be pursued now, and then augmented going forward as new information becomes available.

Forum participants offer seven recommendations for influencing consumer behavior and attitudes.

<u>Recommendation 2.1</u>: Shift the emphasis of marketing. The marketing of lower-calorie and less-calorie-dense foods should increase, accompanied by a reduction in marketing that highlights higher-calorie (or calorie-dense) foods or encourages large portions.

Companies, government, health organizations, and others should expand and align marketing initiatives (both commercial and social) that help consumers to manage their calorie intake. Foodservice companies and venues should use their full range of creativity and resources to promote food choices and eating behaviors that are consistent with healthy weight management. In addition, companies, government, health organizations, and others should conduct market research to determine:

- how best to market low-calorie and less-calorie-dense menu options to different populations in ways that assist consumers with weight management efforts, and
- how to shift the prevailing value proposition away from large portions, and how best to market more appropriate portion sizes to different populations.

<u>Recommendation 2.2</u>: Update marketing standards. Industry, government, health and nutrition experts, consumer representatives, and other stakeholders should work together to review and update standards for marketing away-from-home foods to children.

The Children's Advertising Review Unit (CARU), which is funded by members of industry, could work with key stakeholders from the public, private, and civic sectors to review and update its standards for marketing to children, including the marketing of away-from-home foods. CARU maintains self-regulatory guidelines for children's advertising, and as of this writing has announced an extensive and consultative review of those guidelines.

Recommendation 2.3: Promote low-calorie-dense dietary patterns. Strengthen and/or create education and promotion programs regarding away-from-home foods that promote the consumption of fruits, vegetables, no- and low-fat milk and milk products, whole grains, and foods low in saturated fats and trans-fatty acids, as recommended by the 2005 Dietary Guidelines for Americans.8

For example, the national 5 A Day for Better Health program could be significantly expanded and strengthened, and the U.S. Department of Agriculture (USDA) could create a federal marketing matching program for promoting fruits and vegetables. Federally sponsored consumer research could be undertaken to develop behavior change strategies for closing the gap between recommended intakes and current consumption.

The Milk Matters program at the National Institute of Child Health and Human Development, as well as the Powerful Bones, Powerful Girls program at the Centers for Disease Control and Prevention, could also be significantly expanded and strengthened to build skills for selecting foods and beverages away from home. The programs could include a large-scale social marketing campaign to promote the intake of three daily servings of low-fat and nonfat milk and milk products, consistent with the Dietary Guidelines.

Recommendation 2.4: Promote enhanced "lifestyle education" programs. Use a combination of social marketing campaigns and consumer education programs to provide "healthy lifestyle" education to help individuals eat more healthfully in today's food environment. Existing campaigns and programs could be enhanced or, as necessary, new ones could be created.

Both campaigns and programs in various sectors should aim to help individuals understand how to make decisions within the food environment healthfully—i.e., how to navigate the wide range of away-from-home food choices available in today's often harried, time-pressed, conveniencedriven world. A social marketing campaign should focus on those areas with the most supporting evidence and strongest justification for action. For example, a campaign could seek to change the social value proposition of "more food" to "better-quality food," and/or to promote the concept of energy balance—i.e., balancing caloric intake with physical activity expenditure.

Recommendation 2.5: Review the effectiveness of existing programs. The U.S. Department of Health and Human Services (HHS) and the USDA should, in partnership together, coordinate a comprehensive survey and analysis of existing government-sponsored education and social marketing campaigns related to managing weight gain and reducing obesity in the context of away-from-home foods.

With HHS and USDA as the coordinators and conveners, key federal agencies should pool resources to sponsor a systematic survey and analysis of education and social marketing campaigns directed at consumers who are trying to manage weight gain and obesity. Individual

The Keystone Forum on Away-From-Home Foods—Final Report

⁸ U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA), *Dietary* Guidelines for Americans 2005 (6th ed.) (Washington, DC: HHS and USDA, 2005).

⁹ "Social marketing" programs typically seek to improve personal or societal welfare—for example, by promoting healthy eating, active living, avoidance of illegal drug use, or proper use of seat belts.

agencies should be responsible for analyzing the programs they administer. A standard evaluation tool should be developed for assessing the relative success of each program in helping consumers with healthy weight management.

The analysis should seek to identify the target audiences (and any key audiences that have been missed), the kinds of programs implemented, and their effectiveness against criteria developed by the study team, such as ease of understanding by consumers, consumers converting that understanding to action, and costs. The analysis should offer recommendations for how to streamline government efforts to use resources more efficiently, increase the frequency and consistency of messages, and ultimately, more effectively influence consumers' behavior.

<u>Recommendation 2.6</u>: Improve government access to data on consumer behavior and attitudes. Federal agencies should act immediately to increase the access of government researchers and policymakers to syndicated commercial databases. Key agencies should establish recurring line items in their respective budgets, thereby ensuring continual and timely access to the needed commercial data sets.

Key agencies should coordinate needs and resources in order to purchase relevant commercial data sets from syndicated research organizations. Interagency collaboration is needed to ensure adequate funds for an initial purchase, to promote coordinated policies and programs that result from an analysis of the data, and to encourage the widest possible access to the data.

<u>Recommendation 2.7</u>: Ensure public availability of information. A means must be developed for continually improving the publicly available knowledge base regarding consumer interests, attitudes, and behaviors regarding away-from-home foods.

Since government access to commercial data sets, while very important, is typically accompanied by nondisclosure terms that may limit direct analysis of the data by other stakeholders, a collaborative research agenda could also be developed to allow for wider access to timely information regarding consumer behavior and attitudes in the area of away-from-home foods. Alternatively, the scope of existing data-gathering initiatives could be expanded to provide more detail regarding behaviors and attitudes regarding away-from-home foods, both nationwide and within key demographic groups. Data should not only be collected, but it should be analyzed and shared with the public, policymakers, health professionals, and other interested stakeholders.

Chapter 3: Increasing the Availability of Lower-Calorie Products, Menu Items, and Meals

The foodservice industry faces a number of challenges in its efforts to provide menu items and meals that help consumers effectively manage their calorie intakes and thus maintain healthy weight. These challenges can be viewed as opportunities for the industry to take a proactive role in combating the national problem of overweight and obesity. With this in mind, Keystone Forum participants sought to propose some achievable, action-oriented strategies for the foodservice industry, including bold and innovative approaches (in which taste was a non-

negotiable "must") with regard to products, menu items, and meal choices, to assist consumers with managing calorie intake.

To address the Forum's goal of reducing obesity, the recommendations and operational tips provided in the report focus on manipulating the calorie content, including the calorie density, of menu items and meals through several strategies: providing appropriate portion sizes, plate composition, menu pairing, and beverage options; increasing fruits and vegetables; reducing total fat content; and decreasing the use of ingredients that are high in refined starches, added sugars, and saturated and trans fats and low in nutrient density.

Forum participants articulated four recommendations, directed primarily at the foodservice industry, to address these issues. The recommendations are followed by specific operational tips, which are meant to serve as examples of how the recommendations could be implemented and should not be considered all-inclusive.

<u>Recommendation 3.1</u>: Promote the wider inclusion in foodservice of less-calorie-dense menu items and calorie-sparing cooking techniques that are widely accepted by consumers and that take into account constraints on operators.

To implement this recommendation, Forum participants believe that culinary educational facilities should provide chefs and foodservice operators with the necessary education, resources, and skills to produce menu choices that will help customers achieve and maintain a healthy weight. They should, for example, provide educational programs that illustrate how to develop less-calorie-dense menu items and that overcome the perception that healthy menu items lack creativity and flavor. Chefs and restaurateurs should also be encouraged to offer more lower-calorie choices on children's menus.

In addition, appropriate government agencies should, in conjunction with industry, stimulate initial educational and leadership efforts. They should provide grants to help culinary schools develop curricula or other resource materials that reflect the current consensus within the scientific community about cooking methods and approaches that help consumers achieve and maintain a healthy weight.

Finally, the synergy between producers/manufacturers, distributors, and operators should be enhanced, in order to facilitate the purchase and use of the products that are needed to produce new or reformulated menu items and meals, to help consumers manage their energy intake. Chapter 3 suggests numerous ways this could be done; for example, industry leaders and appropriate government agencies should encourage manufacturers to offer foodservice-size packaging for products such as evaporated fat-free milk, lower-fat cheeses, and precut vegetables, all of which can be used to make less-calorie-dense menu items.

<u>Recommendation 3.2</u>: Foodservice providers should develop and promote portion-size, plate composition, and menu-pairing options that help consumers in their efforts to manage their energy intake.

The chapter offers numerous implementation strategies geared toward chefs, menu developers, servers, and customers. For example, these individuals are encouraged to:

- Reduce total calories in mixed dishes by combining moderate reductions in calorie density with changes in portion size.
- Retool menu items to provide lower-calorie-dense choices.
- For sandwiches, offer more fruit and/or vegetable options than just lettuce and tomato. For example, offer roasted red peppers, roasted eggplant, cucumbers, etc.
- Provide more options and promote meal bundles with fruits and vegetables (including salads), while maintaining traditional side options as well.
- Offer several portion sizes of each menu item.
- Adopt approaches to support portion-size reduction and/or curtail emphasis on "bigger means better" messages.

<u>Recommendation 3.3</u>: Foodservice providers should develop, make available, and promote beverage options that help consumers to reduce calorie intake.

To do this, Forum participants suggest that industry leaders:

- Increase the range of low-calorie or zero-calorie beverage choices available to consumers and provide smaller portion sizes (e.g., 10-fluid-ounce sizes, 100-calorie servings, etc.).
- Increase the selection of low-fat or nonfat milk beverages, especially with children's meals.
- In specialty venues such as coffee shops, offer lower-calorie selections and smaller portion sizes of specialty and frozen drinks, in addition to the standard versions.
- Expand the range of beverage options available to consumers to include a wider array of cup and bottle sizes.
- Consider pricing approaches that make smaller sizes and lower-calorie options more appealing.
- For bundled meals, offer lower-calorie beverage options, such as water, and encourage reasonable portion sizes.

<u>Recommendation 3.4</u>: Industry and academia should conduct—collaboratively, if possible—research on the topics and questions listed in Chapter 3. In addition, a specific scientific survey should be conducted about the experiences of operators and restaurateurs in developing menu items that could aid in weight management.

Chapter 3 sets forth a number of potential research questions that should be addressed through collaborative research. The questions address basic research needs as well as suggestions for the development of specific, scientifically sound strategies that will lead to a better-informed public, industry, and academic community. The questions are categorized into four topics: calorie density and portion size; increasing fruits and vegetables; product formulation; and packaging and marketing.

In addition, a scientifically rigorous survey should be conducted after the conclusion of the Forum to gather information from chefs and restaurant owners about their experiences helping customers to manage their weight and health, particularly via product reformulation and innovation.

Chapter 4: Providing Consumers with Nutrition Information

When making decisions about away-from-home foods, consumers often may not have access to nutrition information to inform their selections and eating behaviors pursuant to appropriate calorie intake. Whereas a growing number of foodservice venues voluntarily provide some information about the calorie and nutritional content of their menu items, many do not. Available information may be provided in different formats (e.g., websites, brochures, kiosks), focus on a variety of nutrients (e.g., calories, carbohydrates, fat), and take a variety of forms (e.g., numerical values, symbols, written characterizations of health attributes). In the absence of any nutrition information, consumers typically are unable to assess the caloric content of foods.

Forum participants offer the following two recommendations regarding the provision of nutrition information to consumers.

<u>Recommendation 4.1</u>: Away-from-home food establishments should provide consumers with calorie information in a standard format that is easily accessible and easy to use.

Forum participants believe that information should be provided in a manner that is easy for consumers to see and use as part of their purchasing and eating decisions. Information should be provided for any standard menu item offered on a regular and ongoing basis that is prepared from a standardized recipe, whether the item is an entire meal or a meal component. Non-standard items, including daily specials and experimental items, may be exempted. Information should be provided for the standard menu item as usually offered for sale (i.e., the base product, in the portion size as offered for sale), since most means of providing information cannot easily account for changes due to customization and special orders. Also, information should be accompanied by a caveat regarding variations owing to preparation, customization, and server variability.

Single-store operations and small chains may not be able to provide nutrition information. Other foodservice venues, such as contract dining services, that have variations in sourcing and preparation, or that do not have standard menus, may also have difficulty providing information that is accurate, reliable, and consistent. However, restaurants and other foodservice operators are encouraged to provide the information to the extent feasible.

In addition to these implementation tips, the chapter's discussion of Recommendation 4.1 addresses the cost of providing nutrition information, methods of nutritional analysis, means of delivering the information, possible unintended consequences, and considerations regarding the provision of nutrition information beyond calories, children's needs, and the accuracy of the information.

Recommendation 4.2: Research by multiple sectors should be conducted on how consumers use nutrition information for away-from-home foods; how this information affects their calorie intake at that venue; how and why nutrition information affects operators' decisions, costs, and revenues; and unanticipated consequences.

There is a clear need for more research regarding how the provision of nutrition information, claims (such as "low calorie"), and symbols influence consumer preference and choice for away-from-home food consumption situations. Of particular concern is how, when, and why consumers use nutrition information and claims during their decision-making processes. More specifically, a better understanding is needed of the types of factors that moderate consumers' responses to the provision of nutrition information and claims for away-from-home foods. The chapter concludes with a list of suggested research questions for addressing these topics.

Taken together, the recommendations in this report address important challenges, and also provide opportunities for multiple sectors to have a positive impact on the task of helping consumers manage their energy intake with respect to away-from-home foods. It is hoped that all sectors—public, private, and civic—can take action based on these recommendations and implementing strategies to help address the growing problem of obesity in the United States.

Introduction

Over the past two decades in the United States, obesity has become a public health crisis of epidemic proportions. At present, approximately 64% of all U.S. adults are overweight, including 30% who are obese. Overweight and obesity are associated with increased morbidity and mortality, and also exact significant economic costs. The medical expenses attributable to overweight and obesity are estimated to have reached as high as \$92.6 billion per year—roughly 9.1% of total U.S. medical expenditures.¹⁰

A number of efforts to address and reverse this public health crisis have been and are being undertaken in the public, private, and nonprofit sectors. This report is the final work product of one such effort—the Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity.

The Keystone Forum has been unique in two ways. First, it brought together a wide diversity of participants in a spirit of collaborative problem-solving. The participants included representatives from the restaurant, on-site contract dining, food manufacturing, and grocery industries; consumer and patient advocacy organizations; the federal government (including the Food and Drug Administration (FDA), the Centers for Disease Control and Prevention (CDC), and the Federal Trade Commission); academia (from the fields of medicine, nutrition, and economics); a local public health department; professional societies; and voluntary health organizations. (A complete list of participants can be found in Appendix A.) Throughout the process, participants sought to share information, explore each others' views, and work toward consensus recommendations that will advance the interests of public health in terms of reducing obesity and overweight.

Second, the Forum focused exclusively on "away-from-home foods"—foods prepared and purchased away from home. A recent report produced by the FDA—titled *Calories Count:* Report of the Working Group on Obesity—highlighted the importance of considering awayfrom-home foods in efforts to control obesity:

In light of the growing proportion of American meals consumed outside of the home, it is important to enlist the assistance and support of restaurants in addressing population obesity. Since the late 1990s and projecting through 2004, American households are spending approximately 46% of their total food budget on food consumed outside the home. 11 During 1994-1996, food consumed outside the home, especially from restaurants and guick-service food establishments, contributed 32% of daily intakes of energy calories, 32% of added

¹⁰ E.A. Finkelstein, I.C. Fiebelkorn, and G. Wang, "National Medical Spending Attributable to Overweight and Obesity: How Much, and Who's Paying?" Health Affairs W3 (2003): 219-226. See www.cdc.gov/nccdphp/ dnpa/obesity/economic consequences.htm.

The Keystone Forum on Away-From-Home Foods—Final Report

¹¹ Economic Research Service (ERS), "Table 1: Food and Alcoholic Beverages: Total Expenditures," Food CPI, Prices, and Expenditures (Washington, DC: ERS, 2003), cited in U.S. Food and Drug Administration (FDA), Calories Count: Report of the Working Group on Obesity (Washington, DC: FDA, 2004) (see www.cfsan.fda.gov/~dms/owg-toc.html); and National Restaurant Association, "2004 Restaurant Industry Forecast Executive Summary," www.restaurant.org/research/ forecast.cfm, cited in FDA, Calories Count, 2004.

sugars, and 37% of fat. 12 Thus, food consumed away-from-home is an important part of American diets, and more informed dietary choices away-from-home could help reduce calorie over-consumption and the risk of obesity and its associated health problems.¹³

It was this same *Calories Count* report that spurred the formation of the Keystone Forum on Away-From-Home Foods. The report recommended that the FDA "work through a facilitator to provide a forum for stakeholders to seek consensus-based solutions to specific aspects of the obesity epidemic." ¹⁴ In response, the FDA in June 2004 asked The Keystone Center—a neutral, nonprofit dispute resolution and public policy organization—to design, convene, and facilitate a forum on away-from-home foods and opportunities for assisting consumers in preventing undue weight gain and obesity.

This report summarizes Forum participants' findings and recommendations. It is hoped that the American public will be the ultimate beneficiary of the Forum's work. Toward that end, Forum participants expect that the report will be useful to a broad array of potential implementers and interested stakeholders, including foodservice operators and their suppliers, policymakers, public health and medical professionals, culinary professionals, patient and consumer advocates, research scientists, and others. The specific intended audiences for the report vary by section and by recommendation.

The Forum Process

The Keystone Forum on Away-From-Home Foods commenced in December 2004 with a smallgroup planning meeting. The first full-group plenary session was held over the course of two days in April 2005. At that meeting, Forum participants agreed to organize themselves into three work groups in order to address key topics more fully: Consumer Behavior; Products, Menu Items, and Meals; and the Market and Policy Environment. Other work groups and ad hoc small groups subsequently formed to address issues relating to nutrition information, marketing, pricing, and children's needs. The work groups "met" via conference call and e-mail on numerous occasions, and two more plenary sessions were held—one in July 2005 and one in November 2005. All of the plenary sessions were held in Washington, DC. Substantial portions of the first two plenary meetings were open to invited observers; the meetings were otherwise closed for deliberation. Over time, the group moved from information exchange to deliberation to the drafting of proposals, which ultimately led to this final report.

The Keystone Forum on Away-From-Home Foods was convened and facilitated by The Keystone Center, a nonprofit organization with offices in Colorado and Washington, DC. 15 The Keystone Center specializes in bringing together people from the private sector, nongovernmental organizations, academia, and government to address pressing questions and

¹² ERS, "Table 5: Daily Food Consumption at Different Locations: All Individuals Ages 2 and Older," *Daily Diet* and Health: Food Consumption and Nutrient Intake Tables (Washington, DC: ERS, 2000), cited in FDA, Calories Count, 2004.

¹³ FDA, Calories Count, 2004.

¹⁴ Ibid.

¹⁵ See www.keystone.org.

develop consensus on public policy issues that would be difficult to resolve within traditional decision-making processes. The Consensus Building Institute provided additional facilitation expertise, and Larmer Consulting assisted with the compilation and editing of this report. 16 The project was funded solely by the FDA. (The content of this publication does not necessarily reflect the views or policies of the U.S. Department of Health and Human Services, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government.)

Keystone Forum participants agreed throughout the process to abide by a set of "operating protocols," which outlined objectives, roles, responsibilities, and a number of discussion principles. Among the principles, for example, participants agreed to keep the discussions civil and constructive, offer solutions rather than just criticisms, keep an open mind, and so forth. Under these protocols, participants had the opportunity to develop a common understanding of the issues, explore their respective interests, and clarify options to help inform future action by decision-makers within industry, government, and civil society. Participants were asked to represent their personal views in the discussions and were understood to be speaking on behalf of themselves and not on behalf of their organizations or constituencies, unless they otherwise indicated.

This report is designed to be an accurate portrayal of Forum participants' discussions and recommendations. By including their names in Appendix A, Forum participants are indicating that they "generally support" the recommendations and overall content of the report, though they may find some sections more acceptable and compelling than others. Therefore, participants may heartily endorse specific sections even while they continue to have concerns or questions about others. During the process of developing this report, greater weight was placed on building agreement around the recommendations, supporting rationales, and suggested implementation steps than around the narrative text that provides background and contextual information. For some topics on which the group did not reach agreement, the various perspectives are characterized.

Participants' organizations are listed in Appendix A for identification purposes only; the listing of an organization's name is not meant to imply official support of the report. Also, participants do not necessarily endorse specific studies or reports cited in this report.

To assist the group in considering specific topics, individual participants or groups of participants frequently consulted existing available literature, and in some cases conducted interviews. This report is not intended to be an "evidence-based report" per se, and participants recognize that additional public or proprietary research may exist that they did not identify or were unable to access. The group also recognizes both that additional research is needed to strengthen the knowledge base regarding many issues addressed by the Forum, and that reasonable strategies should be pursued on the basis of the best information available.

¹⁶ See www.cbuilding.org and www.larmerconsulting.com.

The Forum's Purpose, Objectives, and Context of Inquiry

From the outset, the stated purpose of the Keystone Forum on Away-From-Home Foods was to consider what can be done, given what is currently known, to support consumers' ability to manage energy intake with respect to preventing undue weight gain and obesity, within the scope of away-from-home foods.

The objectives of the Keystone Forum were to:

- Identify the state of the evidence, as well as important knowledge gaps, regarding obesity and weight gain prevention and away-from-home foods. (Forum participants were interested in understanding both consumer choice and the environment in which consumers make choices.)
- Identify current opportunities and promising areas of action for preventing weight gain and obesity.
- Identify means for evaluating possible actions.
- Identify areas and opportunities for collaboration across sectors.
- Encourage the formation of collaborations necessary to pursue recommendations.
- Encourage participants and others to take action, as feasible and appropriate, to help people manage their caloric intake from away-from-home foods.
- Disseminate the results of the Forum to other parties who might contribute to implementing the recommendations.

Keystone Forum participants recognize that obesity is a systemic, societal problem requiring a multifaceted set of solutions, and therefore the group did not attempt to assign blame to organizations or individuals. Rather, all participants agreed to work in good faith and with open minds toward collaborative solutions to this shared problem.

Forum participants also agreed to consider the role of food in the context of what is known about obesity—in other words, in light of the fact that food, wherever consumed, is a major factor but not the only factor causing obesity. Because obesity and undue weight gain result from sustained energy imbalance, physical activity is also an essential element in obesity prevention and treatment. While this inquiry focused on food choice and consumption, participants recognized that the broad societal effort to reduce obesity incidence must consider both sides of the energy balance equation.

The Scope of the Discussions

The Forum's discussions focused on obesity and away-from-home foods. As in the FDA's *Calories Count* report, the term *obesity* was used to refer to overweight and obesity together. ¹⁷ Similarly, the term *foods* is frequently used in this report to refer to both foods and beverages.

¹⁷ The National Institutes of Health define "overweight" in adults as a body mass index (BMI) of 25.0 to 29.9 and "obesity" as a BMI of 30.0 or higher. BMI is defined as the ratio of a person's bodyweight in kilograms divided by the square of his or her height in meters. See www.nhlbi.nih.gov/health/public/heart/obesity/lose_wt/risk.htm#limitations.

The term *away-from-home foods* was used to denote foods prepared and purchased away from home (including take-away foods) that are not generally subject to current federal regulations for food labeling. Such foods include full meals as well as single ready-to-eat items. Points of purchase include restaurants, prepared-food counters at grocery stores, convenience stores, and a variety of institutional foodservice settings.

The report in general does not single out any particular subgroup of the U.S. population. However, participants acknowledged the unique concerns relating to children, since that population group faces significant long-term health consequences due to the epidemic of overweight and obesity. The prevalence of obesity among children and adolescents in the United States has doubled in the past two decades. Now among 6- to 11-year-olds, 13% are above the 95th percentile for body mass index (weight for height), and among 12- to 17-year-olds, 14% are above the 95th percentile, with even higher rates among subpopulations of minorities and the economically disadvantaged. Data from the CDC also indicate that even children less than five years old across all ethnic groups have had significant increases in the prevalence of overweight and obesity. Some recent studies suggest an association between eating away from home and overweight and obesity in children and adolescents. Although a direct causal relationship between away-from-home foods and childhood obesity has not been established, it is clear that away-from-home foods are a significant contributor to the overall energy intake of many children; therefore, the role these foods play in children's nutrition should be examined.

At the outset of this Forum, it was determined that the topic of school meals would not be included in the scope of the discussions. Participants noted that school meals constitute a significant source of calories for school-aged children; approximately 6.5 billion meals are served annually under the jurisdiction of the U.S. Department of Agriculture school meal programs.²⁴ However, the Forum generally did not consider school meals for the following reasons: (1) there was a need to limit the scope of the dialogue to a manageable area of inquiry that could be addressed productively during the course of three plenary meetings; (2) some participants believed that an FDA-sponsored dialogue could focus most productively and

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¹⁸ Note that the Forum's working definition of "away-from-home foods" aligns more closely with that of the U.S. Department of Agriculture's Economic Research Service than it does with that of the USDA's Agricultural Research Service, which does not include take-away or delivered foods consumed at home.

¹⁹ C.L. Ogden, et al., "Prevalence and Trends in Overweight among U.S. Children and Adolescents, 1999-2000," *Journal of the American Medical Association* 288 (2002): 1728-1732.

²⁰ R.P. Troiano, et al., "Overweight Prevalence and Trends for Children and Adolescents," *Archives of Pediatrics and Adolescent Medicine* 149 (1995): 1085-1091.

and Adolescent Medicine 149 (1995): 1085-1091.

²¹ Z. Mei, et al., "Increasing Prevalence of Overweight among U.S. Low-Income Preschool Children: The Centers for Disease Control and Prevention Nutrition Surveillance, 1983 to 1995," *Pediatrics* 101 (1998): e12; and C.L. Ogden, et al., "Prevalence of Overweight among Preschool Children in the United States, 1971 through 1995," *Pediatrics* 99 (1997): e1.

²² E.M. Taveras, et al., "Association of Consumption of Fried Food Away from Home with Body Mass Index and Diet Quality in Older Children and Adolescents," *Pediatrics* 116 (2005): e518-e524; and O.M. Thompson, et al., "Food Purchased Away from Home as a Predictor of Change in BMI Z-Score among Girls," *International Journal of Obesity* 28 (2004): 282-289.

²³ B.H. Lin, J. Guthrie, and E. Frazao, "American Children's Diets Not Making the Grade," *FoodReview* 24 (2001):

²³ B.H. Lin, J. Guthrie, and E. Frazao, "American Children's Diets Not Making the Grade," *FoodReview* 24 (2001) 8-17.

²⁴ See USDA, "National School Lunch Program: Participation and Lunches Served," www.fns.usda.gov/pd/slsummar.htm, accessed March 29, 2006; and USDA, "School Breakfast Program Participation and Meals Served," www.fns.usda.gov/pd/sbsummar.htm, accessed March 29, 2006.

appropriately on aspects of the obesity problem that fall within the FDA's core capabilities and areas of activity; and (3) the topic of foods consumed in schools is sufficiently complex and important (and the parties involved sufficiently different in many cases) to merit treatment in a separate dialogue. In fact, several notable efforts are already underway, including a newly formed Institute of Medicine committee on nutrition standards for foods in schools, which has a report due out in 2006.²⁵ Nonetheless, it was believed by many participants that some discussion of specific considerations for children was in order, particularly in relation to menu development, providing nutrition information, and food marketing to children. Therefore, some of the recommendations that follow in this report include consideration of children's unique needs.

Key Concepts: Calorie Density and Nutrient Density

Two terms—calorie density and nutrient density—warrant some explanation, as they underlie the Forum's approach to calorie intake in the area of away-from-home foods. Calorie density (also known as energy density) refers to the amount of calories (i.e., energy) contained in a unit of food (measured by weight, e.g., kcal/g).²⁶

Nutrient density refers to the amount and availability of nutrients in a unit of food.²⁷ Knowing the nutrient density of foods allows for the comparison of nutritional value among different foods, regardless of serving size. Nutrient-dense foods provide substantial amounts of vitamins and minerals, and relatively fewer calories. Foods low in nutrient density supply calories but relatively small amounts of nutrients (or sometimes none).²⁸

The Forum focused on assisting consumers with managing appropriate caloric intake pursuant to obesity prevention. However, several sections of this report refer to the concept of nutrient density and the importance of various nutritional considerations, to avoid the implication that calories are the only nutritional consideration for a healthy diet. While appropriate caloric intake is essential to addressing the problem of obesity, it is also important for consumers to get the most nutritional value from their calories.

Considerations in Developing Recommendations

Keystone Forum participants developed the following considerations for assessing options to address the current obesity epidemic.

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²⁵ Institute of Medicine, "Nutrition Standards for Foods in Schools," www.iom.edu/CMS/3788/30181.aspx, accessed March 18, 2006.

²⁶ See www.health.gov/dietaryguidelines/dga2005/report/HTML/G1_Glossary.htm. While *energy density* and *calorie density* can be used interchangeably, this report generally uses the latter term.

²⁷ See www.diet-and-health.net/glossary.html. For an extensive review of literature on nutrient density, see A. Drewnowski, "Concept of a Nutritious Food: Toward a Nutrient Density Score," *American Journal of Clinical Nutrition* 82, no. 4 (2005): 721-732.

²⁸ Modified from the International Food Information Council's glossary of food-related terms at www.ific.org/glossary/glossarynz.cfm. See also www.health.gov/dietaryguidelines/dga2005/report/HTML/G1 Glossary.htm.

- 1) Various rationales exist for policymakers and others to consider in acting to protect or improve public health. They include, but are not limited to, a favorable cost/benefit ratio, a substantial basis for believing that the action will have the desired effect, and the need to take preventative measures in the face of uncertainty.
- 2) Obesity prevention strategies ought to be guided by robust and relevant scientific evidence, though science alone is not the deciding factor.
- 3) Individual choice should be respected.
- 4) Broad environmental changes need to address both supply and demand. The supply side includes increasing the choices of healthier and less-calorie-dense menu items and meals available in foodservice establishments. Because commercial enterprises are unlikely to subsidize menu items that sufficient numbers of consumers do not want, demand-side considerations include influencing consumer choice through education, marketing, and other means
- 5) Decision-makers should be cognizant of the potential unintended consequences of intervening in an area as complex as the eating behavior of individuals.
- 6) The need for additional research should not preclude reasonable action. As noted in the Institute of Medicine's 2004 report, *Preventing Childhood Obesity: Health in the Balance*, "[t]he obesity epidemic is a serious public health problem that calls for immediate action to reduce its prevalence as well as its health and social consequences. Therefore...actions should be based on the best available evidence—as opposed to waiting for the best possible evidence."²⁹

With regard to this last consideration, the best available evidence for obesity prevention and control is grounded in a solid, well-documented knowledge base regarding energy balance. Keystone Forum participants believe that what is needed now is reasonable guidance and action to help make healthy food choices easier for individuals and families.

Decision-makers do not always have the luxury of operating on the basis of absolute scientific certainty. In the prevention and control of obesity, Forum participants agree that we do not have the luxury of waiting for a perfect scientific evidence base for each setting- or population-specific weight-control strategy that could influence an individual's energy balance. As is frequently the case in responding to public health challenges, judgment calls must be made in light of the potential benefits and costs of taking action, and the potential costs of not acting.

All segments of society share responsibility for changing the course of the obesity epidemic. Education and personal responsibility are important parts of the solution, as are changes to the environment in which individuals and families make decisions. The restaurant industry, foodservice professionals, culinary institutions, and food distributors can support an individual's decision-making by expanding opportunities for consumers to effectively manage their energy intake.

In developing recommendations along these lines, Forum participants adopted a "language hierarchy" for assigning weight to each proposed strategy or action. Participants agreed that, in a recommendation:

²⁹ Institute of Medicine, *Preventing Childhood Obesity: Health in the Balance* (Washington, DC: National Academies Press, 2004).

- "shall" indicates an action meant to be mandated, required, regulated, or demanded;
- "should" indicates an action that is desired, preferred, or sought; and
- "may" indicates an action that one could or might consider—i.e., one of many reasonable options.

This report relies upon the language and spirit of "should" and "may" and avoids use of the word "shall," in keeping with the voluntary nature of the Forum's purview.

Funding the Recommended Actions

Many of the actions recommended by the Forum will require significant resources for implementation. For example, funds will be needed to design and launch (or expand) programs, to assess the effectiveness of various strategies, and to conduct research.

The government, foundations, foodservice companies, and civic-sector organizations can all play a significant role in sponsoring new or enhanced initiatives. Collaborative approaches should be sought where feasible between diverse organizations and sectors, since some actions may be cost-prohibitive if undertaken individually. Some coordination of program resources is already happening within the restaurant industry, among voluntary health organizations, and by organizations such as the Produce for Better Health Foundation. Ultimately, strategies for obesity prevention in the area of away-from-home foods will necessitate broad support and participation from government, the private sector, philanthropies, and civil society.

Chapter 1 Setting the Stage

To set the stage for the chapters that follow, this chapter first describes a number of themes regarding today's business and consumer environment, and then provides some discussion and data on how that environment has changed over the past several decades. The final section in this chapter discusses the relationship of away-from-home foods to body weight.

Key Themes

During months of dialogue and joint consideration of various potential strategies and rationales, Forum participants articulated the following themes regarding today's business and consumer environment. The type and degree of evidence underlying each assertion varies.

- 1) The health outcomes and health costs of overweight and obesity are critical public health concerns.
- 2) The environment in which consumers make food choices (including regarding away-fromhome foods) has changed dramatically in the last 30 years. (This assertion is explored more fully in the next section.)
- 3) Domestic agricultural production and imports provide Americans with a wide variety of foods in abundance. It is uncertain whether changing U.S. agricultural policy in ways that affect production patterns would significantly alter American consumers' choices; this may depend on the scale of the changes. For example, it is unclear if shifts in U.S. agricultural policy to encourage greater consumption of fruits and vegetables could affect the availability and pricing of those foods, and what unintended consequences that would have for farmers and their customers. On the other hand, American consumers' changing tastes and preferences certainly affect farmers' production decisions season-to-season and over time.
- 4) As with any large industry sector, the away-from-home foods sector both responds to consumer demand and seeks to shape and influence that demand by what is offered, how it is offered and priced, and how it is marketed and advertised.
- 5) Given that even modest increases in calories consumed can have long-term, significant effects on weight and obesity, it is difficult to determine the degree to which various changes in today's environment are responsible for the growing problem of obesity.
- 6) The research base on obesity is incomplete and imperfect regarding some aspects of the problem, such as the potential effectiveness of specific interventions aimed at assisting consumers with managing their energy intake. While Forum participants propose several priorities for further research, they also recognize that perfect information may never be

possible in some areas given the complexity of the obesity problem and the many variables involved in consumer behavior.

- 7) Unintended consequences may result from acting on the basis of imperfect knowledge.
- 8) Psychological and social factors (such as comfort, indulgence, nostalgia, celebrations, and social contact) play a large role in how people eat, including when eating away-from-home foods.
- 9) As of this decade, Americans are eating out more frequently and consuming more calories from away-from-home establishments than ever before. Thus, it is assumed that a wider range of less-energy-dense, more-nutrient-dense food and beverage choices in away-from-home food outlets, coupled with consumer education and information (especially about energy balance), can help Americans to manage their weight more effectively.
- 10) To address weight gain in the United States, the current general consumer value proposition should shift away from an emphasis on large-quantity, calorie-dense, low-cost foods and beverages. Adequate physical activity will also need to be an essential part of the solution, to help ensure that individuals increasingly can balance their energy expenditure with their energy intake.
- 11) Many considerations affect people's food decisions in addition to health and nutrition, including convenience, availability, affordability, and satisfaction. In addition, it is not easy for many individuals to change their day-to-day food and activity choices and habits. People often focus more on short-term benefits than longer-term consequences.
- 12) Consumers will respond to nutrition information to varying degrees, ranging from those who actively seek and use such information to make food choices to those who will not use it.
- 13) How overweight and obesity are addressed may have disproportional impacts on diverse populations. Ethnic and cultural factors must be considered. What works in one group may not work in others. Many actions will need to be audience-specific and tailored to specific demographics, geographies, and cultures in order to be effective.

The Changing Environmental Context

On average, Americans are consuming more calories today than they were three decades ago. According to the U.S. Department of Health and Human Services' National Health and Nutrition Examination Survey (an in-person survey), men consumed 2,450 calories per day in 1971, while women consumed 1,542. In 2000, the numbers were 2,618 and 1,877, respectively. Similarly, from food supply data the U.S. Department of Agriculture (USDA) has estimated that average

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³⁰ Centers for Disease Control and Prevention (CDC), "Trends in Intake of Energy and Macronutrients—United States, 1971-2000," *Morbidity and Mortality Weekly Report* 53 (2004): 80-82.

daily per capita energy consumption increased by 12%, or roughly 300 calories per day, between 1985 and 2000.³¹

Many factors have likely contributed to this increase in average caloric intake. Environmental factors—including economic, policy, social, and cultural variables—are among those that affect people's caloric consumption and associated weight and health implications. Other broad factors can be physiological, genetic, and psychological. Understanding the environmental context, however, is an essential part of understanding what choices are available to people and why they make the choices they do.

Among the environmental variables that may affect away-from-home food choices (i.e., that affect why people eat away from home and what and how they eat) are: food costs, technology (production, processing, packaging), consumer demographics (aging, dual-income households, participation of women in the workforce, race/ethnicity), national and household economics (personal disposable income, time use), the availability of quick-service and casual dining restaurants (number and variety), marketing and advertising strategies (amount, quality, effectiveness, types of food marketed, and venue), housing patterns (suburban sprawl), and physical activity expenditures. Many of these environmental variables have changed—some of them dramatically—over the past three decades, as discussed below. Such changes may have had a profound impact on consumers' food choices and eating behavior. ³²

Values and beliefs can also be categorized as environmental factors. For example, many households traditionally ate away from home generally for reasons of celebration, and they viewed the occasion as a special opportunity for indulgence. Today, however, consumer needs and demands—for convenience, affordability, and satisfaction—may be changing faster than relevant consumer values. In other words, people may still subconsciously view dining out mostly as an opportunity for indulgence, even though they are dining out much more often than in the past.

Thus, it is important to consider the environmental context when thinking about the determinants of consumer behavior with regard to away-from-home food and beverage choices. The following are examples of how the environment in which consumers make food choices has changed in recent decades. Some of the examples are specific to away-from-home foods, and some pertain to consumers' broader environment.

• Food on the whole is cheaper for Americans than it used to be. Food expenditure as a percentage of per capita disposable income has fallen.³³

1970
15.3%
2004
10.8%

³¹ J. Putnam, J. Allshouse, and L.S. Kantor, "U.S. Per Capita Food Supply Trends: More Calories, Refined Carbohydrates, and Fats," *FoodReview* 25 (2002): 2-15.

³² See S.L. Booth, "Environmental and Societal Factors Affect Food Choice and Physical Activity: Rationale, Influences, and Leverage Points," *Nutrition Reviews* 59, no. 3 (Part II) (2001): 21-39.

³³ Economic Research Service (ERS), "Table 8: Food Expenditures as a Share of Disposable Personal Money Income," *Food CPI, Prices, and Expenditures* (Washington, DC: ERS, 2003). See www.ers.usda.gov/briefing/CPIFoodAndExpenditures/Data/table8.htm.

• More of Americans' total food budget is used for away-from-home foods. Out-of-home food expenditures as a percentage of total food expenditures per capita have risen.

1970
 26.3%³⁴
 26.0%³⁵
 46.0%³⁵

• Americans now have access to more and more opportunities to select and eat away-from-home foods. The total number of foodservice establishments in the United States has almost doubled in the last three decades.³⁶

1972491,0002004878,000

• According to USDA food availability data, the number of available calories per person in the food supply has increased during this period of time.³⁷

1970-early 1980s
 2000
 3,200-3,300 calories available per person per day
 3,900 calories available per person per day

• Portion sizes in this country have increased both in restaurants and in the home over the past two decades. 38 Although the trend began in the 1970s, larger portion sizes became more common in the 1980s and 1990s. 39

In addition to changes in the food-related aspects of the environmental context over the past three decades, many Americans have experienced broader changes in various lifestyle-related aspects, which may also contribute to the rising incidence of overweight and obesity.

• Both partners in married households are working more, taking away time from numerous other activities, from exercise to meal preparation at home. 40

³⁵ National Restaurant Association, "Restaurant Industry Facts," www.restaurant.org/research/ind_glance.cfm, accessed April 12, 2002.

³⁴ B. Lin, J. Guthrie, and E. Frazao, *Away-From-Home Foods Increasingly Important to Quality of American Diet,* Agriculture Information Bulletin #749 (Washington, DC: ERS, 1999).

³⁶ Personal communication, National Restaurant Association, March 20, 2006. These figures include eating and drinking places and all other categories of commercial and noncommercial restaurant and foodservice establishments. Among the other categories are managed services (contractors), lodging place restaurants, retail hosts, recreation and sports foodservice, school foodservice, health care foodservice, and military foodservice.

³⁷ ERS, "Food Availability Data," www.ers.usda.gov/Data/foodconsumption/FoodAvailIndex.htm, accessed on February 1, 2005.

³⁸ U.S. Bureau of the Census, *Statistical Abstract of the United States: 1985*, 114th ed. (Washington, DC: U.S. Bureau of the Census, 1994); U.S. Bureau of the Census, *Statistical Abstract of the United States: 1994*, 105th ed. (Washington, DC: U.S. Bureau of the Census, 1984); J.O. Hill and J.C. Peters, "Environmental Contributions to the Obesity Epidemic," *Science* 280 (1998): 1371-1374; and H. Smiciklas-Wright, et al., "Foods Commonly Eaten in the United States, 1989-1991 and 1994-1996: Are Portion Sizes Changing?" *Journal of the American Dietetic Association* 103, no. 1 (2003): 41-47.

³⁹ L.R. Young and M. Nestle, "The Contribution of Expanding Portion Sizes to the U.S. Obesity Epidemic," *American Journal of Public Health* 92, no. 2 (2002): 246-249.

⁴⁰ American Sociological Association, *News*, November 22, 2004. As one illustration of the impact of this trend, in 1998 women working outside the home spent an average of 6.3 hours per week on a combination of shopping, cooking, and meal clean-up, compared to 11.5 hours for women not working outside the home. Diego Rose, *Who Has Time to Cook? New Directions for Food and Nutrition Policy Research on Household Meal Production*, a

- o 1970 53 hours for a married couple's combined out-of-home work week
- o 2000 63 hours for a married couple's combined out-of-home work week
- More adults are spending more time commuting each day, diminishing the time available for cooking, exercise, family time, and other activities. The average time commuting to and from work daily, in minutes, has risen.⁴¹

198021.7 minutes each way200024.4 minutes each way

• The variety of venues for product advertising and marketing has proliferated. It includes not only television and print advertising, but also product placement in television shows, films, and video games; toy and other premium give-aways; licensing agreements (tie-ins with television shows and movies); and the internet.⁴²

1970
 \$71.0 million spent on product placement on television
 2004
 \$1.8 billion spent on product placement on television

• Households have the television on almost 25% more than was the case 30 years ago. 43 (This does not take into account time spent in front of computers.)

1970
5 hours 56 minutes per day
2000
7 hours 35 minutes per day

• High school students are less likely to attend physical education class daily than they were a decade ago. 44 The percentage of U.S. schools requiring some form of physical education declines with advancing grade levels, from 50% of 5th grades to only 5% of 12th grades. 45

1991
 2003
 41.6% of high school students attended physical education class daily
 28.4% of high school students attended physical education class daily

The Relationship of Away-From-Home Foods to Body Weight

The question of whether away-from-home foods contribute to overweight and obesity is an important issue that was considered by the Forum. Participants did not seek resolution on this question, but rather focused on proposing implementable solutions to the challenge of obesity. The following is a general overview of existing scientific literature on the subject.

presentation given at the Conference on Food and Eating Consequences of Time-Use Decisions, July 13, 2004. See www.farmfoundation.org/projects/documents/Rose.presentation.pdf.

⁴¹ These figures are from the U.S. Census for 1980 and 2000.

⁴² PQ Media, *Product Placement Spending in Media* (Stamford, CT: PQ Media, 2005).

⁴³ Television Bureau of Advertising, "TV Basics: Time Spent Viewing, Households," data drawn from Nielsen Media Research, NTI Annual Averages, http://www.tvb.org/rcentral/mediatrendstrack/tvbasics/ 08 TimeViewingHH.asp, accessed March 15, 2006.

⁴⁴ CDC, Youth Risk Behavior Surveillance System, "Youth Online: Comprehensive Results: Percentage of Students Who Attended a PE Class Daily," http://apps.nccd.cdc.gov/yrbss/SelectLocyear.asp?cat=6&Quest=511, accessed March 15, 2006. Corresponding national data is not available for younger schoolchildren.

⁴⁵ CDC, National Youth Risk Behavior Surveys, 1991-2003.

While several recent studies have explored various contributors to obesity, as yet there does not exist a conclusive body of evidence establishing a causal link between the use of away-from-home foods and obesity. However, preliminary research indicates that the consumption of away-from-home foods can be a factor in determining calorie consumption and body weight, and an important one for many individuals. An annotated bibliography of studies examining the relationship between away-from-home foods and body weight is provided in Appendix B.

The research methods employed by these studies include: (1) analysis of existing databases, such as the Continuing Survey of Food Intakes by Individuals, the Nationwide Food Consumption Survey, and Coronary Artery Risk Development in Young Adults; and (2) studies of subpopulations, including healthy-weight adults, pre-menopausal women, children, adolescents, and specific ethnic groups. The studies examine indicators such as eating behaviors in various settings; the frequency of away-from-home food consumption and its relationship with calorie and nutrient consumption and occurrence of obesity/overweight; and the association of fast-food consumption within various age, socio-economic, and ethnic groups with overall diet quality, calorie intake, and obesity in those groups.

The consumption-related factors that these studies generally do not consider in-depth include calorie density, serving and portion sizes, liquid vs. solid calories, speed of caloric intake, and activities that might distract from a focus on eating, such as eating while walking, driving, watching television, and working at a computer.

Selected results from these studies include the following.

- Eating out more frequently is associated with obesity, higher body fatness, and higher body mass index. 46
- Women who eat out more often (more than five times per week) consume about 290 more calories on average each day than women who eat out less often. 47
- Eating more fast-food meals is linked to eating more calories, more saturated fat, fewer fruits and vegetables, and less milk. 48

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⁴⁶ M.A. Pereira, et al., "Fast-Food Habits, Weight Gain, and Insulin Resistance (The CARDIA Study): 15-Year Prospective Analysis," *Lancet* 365 (2005): 36-42; E.M. Taveras, et al., "Association of Consumption of Fried Food Away from Home with Body Mass Index and Diet Quality in Older Children and Adolescents," *Pediatrics* 116 (2005): e518-e524; O.M. Thompson, et al., "Food Purchased Away from Home as a Predictor of Change in BMI Z-Score among Girls," *International Journal of Obesity* 28 (2004): 282-289; J.K. Binkley, et al., "The Relation between Dietary Change and Rising U.S. Obesity," *International Journal of Obesity* 24 (2000): 1032-1039; R.W. Jeffery and S.A. French, "Epidemic Obesity in the United States: Are Fast Foods and Television Viewing Contributing?" *American Journal Public Health* 88 (1998): 277-280; and M.A. McCrory, et al., "Overeating in America: Association between Restaurant Food Consumption and Body Fatness in Healthy Adult Men and Women Ages 19 to 80," *Obesity Research* 7 (1999): 564-571.

⁴⁷ L.H. Clemens, et al., "The Effect of Eating Out on Quality of Diet in Premenopausal Women," *Journal of the*

⁴⁷ L.H. Clemens, et al., "The Effect of Eating Out on Quality of Diet in Premenopausal Women," *Journal of the American Dietetic Association* 99 (1999): 422-444.

⁴⁸ Taveras, et al., "Association of Consumption of Fried Food," 2005; M. Schmidt, et al., "Fast-Food Intake and Diet Quality in Black and White Girls," *Archives of Pediatrics and Adolescent Medicine* 159 (2004): 626-631; S.A. Bowman and B.T. Vinyard, "Fast-Food Consumers vs. Non-Fast-Food Consumers: A Comparison of Their Energy Intakes, Diet Quality, and Overweight Status," *Journal of the American College of Nutrition* 23, no. 2 (2004): 163-168; S. Paeratakul, et al., "Fast-Food Consumption among U.S. Adults and Children: Dietary and Nutrient Intake Profile," *Journal of the American Dietetic Association* 103 (2003): 1332-1338; S.A. French, et al., "Fast Food Restaurant Use among Women in the Pound of Prevention Study: Dietary, Behavioral and Demographic

 The daily caloric intake of overweight adolescents tends to increase when they consume fast food; however, lean adolescents tend to have no overall increase in calorie intake when they consume fast food.⁴⁹

Few of the existing studies are longitudinal. The majority of the studies focus solely on quick-service (or "fast") foods. The data available, while consistent in their findings, are not adequate to clearly define the extent of the association between away-from-home foods and body weight, and further research is recommended.

Syndicated commercial data presented to the Forum do not show a correlation between frequency of restaurant use and incidence of obesity and overweight. These data define frequent users as persons who eat from restaurants six times or more in a two-week period. However, it was noted that employing a higher threshold for defining frequent users (e.g., four or ten times per week) might result in a correlation.

In the meantime, the away-from-home foods sector is an important area of inquiry in identifying ways to assist consumers with managing their caloric intake and weight. The percentage of the food dollar spent on away-from-home foods has risen steadily since the mid-1970s,⁵¹ and the percentage of calories obtained from away-from-home foods rose from 18% in 1977-78 to 32% in 1994-96.⁵² The influences on an individual's caloric intake can be many, but how consumers eat when not preparing food for themselves at home is a vital consideration in the broader societal effort to reduce obesity and overweight.

Correlates," International Journal of Obesity 24 (2000): 1353-1359; and Jeffery and French, "Epidemic Obesity," 1998

The Keystone Forum on Away-From-Home Foods—Final Report

⁴⁹ C.B. Ebbeling, et al., "Compensation for Energy Intake from Fast Food among Overweight and Lean Adolescents," *Journal of the American Medical Association* 291 (2004): 2828-2833.

⁵⁰ The NPD Group, presentation to the Keystone Forum on Away-from-Home Foods, April 26, 2005.

⁵¹ J.F. Guthrie, B.F. Lin, and E. Frazao, "Role of Food Prepared Away from Home in the American Diet," *Journal of Nutrition Education and Behavior* 34 (2002): 140-150. See also www.ers.usda.gov/Briefing/DietAndHealth/data/foods/.

⁵² Ibid. See also www.ers.usda.gov/Briefing/DietAndHealth/data/nutrients/table6.htm.

Chapter 2 Understanding and Influencing Consumer Behavior

To reverse the increase in obesity and undue weight gain in the United States, the current consumer preference for large quantities of calorie-dense foods should shift to an emphasis on intake appropriate to an individual's needs and to increased consumption of foods lower in calorie density. However, it can be difficult to change consumers' day-to-day food and activity choices and habits, despite the potential longer-term consequences of those behaviors. Thus, messages and education programs directed at consumers should be carefully crafted; they must impart the knowledge and skills consumers need, and they must reach and motivate consumers successfully. Also, strategies should be tailored as needed to specific demographic and cultural audiences

Much of the existing data and information about consumer eating behavior and attitudes is either not specific to away-from-home foods, not sufficiently timely, or not publicly available. Thus, a research agenda is needed to augment the publicly available knowledge base and inform the continual development of consumer education programs.

It must be stressed, however, that while the knowledge base needs to be improved, enough is known to recommend many important actions. Forum participants believe that reasonable strategies to assist consumers with healthy energy intake should be pursued now, and then augmented going forward as new information becomes available.

This chapter includes: (1) a characterization of what is known about consumer behavior vis-à-vis away-from-home eating; (2) an overview of existing education and marketing efforts seeking to influence consumer behavior; (3) an overview of existing data-collection efforts; and (4) Forum participants' recommendations for understanding and influencing consumer behavior through commercial and social marketing, educational and nutrition promotion, and research.

What Is Known about Consumer Behavior and Away-From-Home Foods

Consumer behavior (what consumers do, how and why they do it, and what might cause them to make different choices) is an extensive, complex field of research that is undertaken in the public, private, and academic sectors. The subset of this research that is both publicly available and relevant to away-from-home foods and obesity prevention is more limited, and should be examined when developing strategies to assist consumers with weight management.

This section provides a brief overview of the following topics relating to the interrelationships among consumer behavior, away-from-home foods, and obesity and overweight.

- Selected trends in consumer behavior and attitudes regarding the purchase and consumption of away-from-home foods
- Selected success factors in the consumer acceptance of recent product innovations that are reduced calorie or less calorie-dense
- An examination of immediate environmental factors that can contribute to excess calorie consumption among consumers

In developing this section, Forum participants drew from four streams of information: government data; syndicated commercial data presented to the group by The NPD Group; industry perspectives collected by Forum participants through a series of informal case studies; and an emerging body of academic research regarding environmental eating cues like portion size and calorie density.

Trends in Consumer Buying, Food Consumption, and Attitudes

Some of the information in this section related to consumer behavior was gleaned from government research into consumer buying patterns and market trends within the away-from-home foods sector. The remaining was drawn from syndicated commercial research data, which are frequently more specific and up-to-date but typically not publicly available.

Some past trends and future projections include the following.

- The frequency of dining out rose by more than two-thirds over the past two decades, from 16% of all meals and snacks in 1977-78 to 27% in 1995. Consequently, a greater proportion of calories and nutrients now come from away-from-home food sources. Away-from-home foods (including foods sold in schools, restaurants, and other venues) provided 34% of total caloric intake in 1995 (nearly double the 18% in 1977-78) and 38% of total fat intake (vs. 18% in 1977-78).⁵³
- The number of meals purchased from a restaurant per person per year increased by 27% between 1984 and 2004.⁵⁴
- Quick-service restaurants had been increasing their share of the away-from-home market until the mid-1990s. In 2002, however, full-service restaurants again accounted for a slightly larger share of total sales.⁵⁵
- Per-capita spending is projected to rise by 18% at full-service restaurants and by 6% at quick-service establishments between 2000 and 2020. 56

Recent behavioral buying patterns of note include the following.

21% of all meals in 2004 were purchased from foodservice establishments.

⁵³ B.H. Lin and E. Frazao, *Away-From-Home Foods Increasingly Important to Quality of American Diet*, Agricultural Information Bulletin #749 (Washington, DC: U.S. Department of Agriculture (USDA), 1999). The 1995 data are included here because they are the most recent, despite being a decade old. The figures will be updated by the National Health and Nutrition Examination Survey in approximately four years.

⁵⁴ The NPD Group, presentation to the Keystone Forum on Away-From-Home Foods, April 26, 2005.

⁵⁵ H. Stewart, et al., *The Demand for Food Away from Home: Full-Service or Fast Food?* Agricultural Economic Report #829 (Washington, DC: USDA, 2004).

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⁵⁷ The NPD Group, presentation to the Keystone Forum, 2005.

- Quick-service restaurants currently make up nearly three-quarters of total restaurant visits.⁵⁸
- Major chains continue to drive industry traffic growth and have constituted about half of total restaurant traffic in recent years.⁵⁹
- The purchase of fresh supermarket take-out foods (e.g., salads) has increased 12% over the past two years. ⁶⁰
- Americans take food from a restaurant more often than they eat on-site.⁶¹
- Approximately one-fifth of restaurant meals were purchased from a car (e.g., drive-through or curbside) in 2005, up from 14% in 1998.⁶²
- The top five most popular foods ordered in restaurants in 2005, for consumption on-site or take out, were:⁶³
 - o For men—hamburgers, french fries, pizza, breakfast sandwiches, and side salads
 - o For women—french fries, hamburgers, pizza, side salads, and chicken sandwiches
 - o For students ages 18 to 24—french fries, hamburgers, pizza, Mexican foods, and chicken sandwiches
 - For children under age 6—french fries, chicken nuggets, pizza, hamburgers, and ice cream
- Foods for which consumption levels increased between 2003 and 2004 included: diet soft drinks, chicken nuggets/strips, french fries, cappuccinos and other gourmet coffee beverages, main dish salads, bottled water, burgers, chicken sandwiches, milk, and Mexican food.⁶⁴
- Foods for which consumption levels decreased between 2003 and 2004 included: regular soft drinks, Chinese/Asian/Indian food, side dish salads, regular coffee, alcoholic beverages, seafood, toast/sliced bread, frozen sweets, cakes, pies, and breadsticks.⁶⁵
- A growing dimension of the restaurant business involves providing "grab-and-go" snacks and regular meals during the afternoon and late at night.⁶⁶
- A household's demand for food away from home depends in part on its income and its demographics. Away-from-home expenditures are typically higher for single-person households and households containing multiple adults without live-at-home children.⁶⁷
- Changes in the workforce, including the rise of dual-income households and the increase in women working outside the home, have fueled the drive for take-out meals, drive-throughs, and convenience in food preparation. ⁶⁸

Attitudes noted in recent research include the following.

 Consumers cite the taste, value, size of portions, and temperature of food as reasons for their increasing satisfaction with major chain restaurants, whereas satisfaction with independent restaurants has declined slightly in recent years.⁶⁹

⁵⁸ Ibid.

⁵⁹ Ibid.

⁶⁰ MSI, The 2005 Gallup Study of Home Meal Replacements (Princeton, NJ: Multi-Sponsor Surveys, Inc., 2005).

⁶¹ The NPD Group, 20th Annual Eating Patterns in America Study (Port Washington, NY: NPD Group, 2005).

⁶² Ibid.

⁶³ Ibid.

⁶⁴ The NPD Group, presentation to the Keystone Forum, 2005.

⁶⁵ Ibid.

⁶⁶ E.A. Sloan, "What, When, and Where America Eats," Food Technology, January 2006.

⁶⁷ Stewart, *The Demand for Food Away from Home*, 2004.

⁶⁸ P.M. Anderson, K.F. Butcher, and P.B. Levine, *Maternal Employment and Overweight Children* (Chicago: Federal Reserve Bank of Chicago, 2002).

⁶⁹ The NPD Group, presentation to the Keystone Forum, 2005.

- 30% of consumers believe restaurant portions are too large. 70
- 62% believe that restaurants do not offer enough small portions.⁷¹
- 61% would like to reduce the amount of food they consume.⁷²

Consumer Acceptance of Recent Product Innovations

Foods that are conducive to healthy energy intake are of no benefit if consumers do not opt for them. During the course of the Forum's dialogue, participants developed a series of informal case studies in an attempt to examine the factors involved in the recent consumer acceptance of certain successful, low-calorie or less-calorie-dense products and concepts. The exercise was not intended to yield findings representative of industry as a whole, but rather to assist the group in generalizing about useful ways to gain consumer acceptance, based on a few important recent examples. The full analysis of the case studies is included with this report as Appendix C.

The case studies were developed largely through telephone interviews and some background research, and they were analyzed by Dave McKechnie and Brian Wansink of Cornell University. The interviewees were asked to provide as much concrete detail about success factors as possible, and they were encouraged to speculate if necessary based on their background and expertise. Most interviewees asked that names and identifying facts be withheld from this report.

The exercise considered recent examples (within the past five years) from a variety of settings: eight from the foodservice industry, one of packaged foods, and one of prepared foods sold in grocery stores. The subjects included both specific product innovations and broad menu innovations, all of which were relevant to weight management in that they were lower in calories (or calorie density or saturated fat) than the products they replaced or than similar products on the market. All of the cases were judged to be successful by the innovating companies, as measured by positive reviews from the media and consumers, imitation by competitors, significantly increased sales, and/or steady sales over time.

Overall, the case studies revealed that the companies involved seem to have found success through a combination of:

- substituting lower-calorie ingredients without compromising taste,
- employing cooking techniques that resulted in fewer calories but yielded strong flavor,
- shifting to contemporary packaging.
- using pre-portioned packaging,
- reflecting trends in consumer health interests, and
- relying on words and phrases that imply healthy attributes, without necessarily using explicitly health-oriented language.

The most significant variables involved in the success of these cases appear to be preparation, packaging, and promotion.

⁷² Ibid.

⁷⁰ M. Allenson, *Consumer Update: What We Want*, presentation at the Technomic Future Industry Directions Conference, June 2005.

⁷¹ Ibid.

With regard to preparation, for example, one family dining chain substituted vegetables for starches and frequently reduced protein portions. A quick-service chain used lower-calorie sauces and condiments for sandwiches, while a grocery chain used lower-calorie dressings for prepared salads. Finally, a fine-dining chain employed grilling and roasting to create strong flavor without the need for heavy sauces; they also featured plate composition emphasizing nutritional balance

With regard to packaging, one lower-fat milk consumption campaign used contemporary packaging to change the perception of the product in consumers' eyes. In another case, a food manufacturer offered several reformulated versions of popular products in pre-portioned 100-calorie packs.

The analysis noted two distinct approaches to the successful promotion and positioning of these products. Some of the companies explicitly responded to current trends in consumer health-related interests in the way the products were positioned and promoted (e.g., "low fat," "better for you"). Some then went on to provide practical frames of reference for the consumer—for example, comparing the product to those of competitors, or highlighting "regular-guy" weightloss success stories.

Other companies, by contrast, used carefully selected words and phrases to imply healthiness without actually using health-related language. They relied instead on terms like "fresh," "locally grown," "not deep fried," and "Mediterranean," as well as taglines like "The Joy of Snacking." By using these types of terms, the companies allowed consumers to make the association with health, while avoiding any suggestion that the product in question might taste inferior to higher-calorie products, or the perception that the product is not satisfying because it is "good for you." Some promotions for products that were—or might be perceived as being—smaller-than-usual portions also emphasized "satisfaction" as an important attribute.

Finally, the analysis posited that consumers may approach different food venues with significantly different mindsets. In a grocery store, a consumer may be more likely to consciously consider value for the dollar in making a choice, but in a restaurant he or she may focus more on taste and satisfaction.

Eating Behaviors—Caloric Intake and Consumers' Immediate Environment

Since obesity is a matter of caloric imbalance, it is essential to identify strategies that can help consumers to understand their food environment and manage their caloric intake. Thus it is important to better understand the drivers of excessive caloric intake. For example, with food in front of them or nearby, what are the immediate triggers or cues that lead many individuals to consume beyond their respective caloric needs?

Recent studies suggest that several factors in the immediate eating environment, including certain properties of foods, affect consumers' eating behavior and are associated with the

overconsumption of calories.⁷³ In particular, increases in the portion size, calorie density (calories per unit of weight), and variety of available foods are all associated with increased calorie intake. If these factors—and the interplay among them—can be properly understood, they can be used in the development of specific strategies to help consumers reduce the excessive consumption of calories. Since most of the studies examining these "eating cues" were conducted in laboratory settings, it is important that similar research be conducted under market conditions as well. Nevertheless, the existing research suggests several useful propositions about why many consumers have difficulty maintaining an appropriate caloric intake.

Portion Size and Caloric Intake

People tend to consume more—both more food and more calories—when presented with larger portions.⁷⁴ The importance of portion size in weight management was stressed in the 2005 *Dietary Guidelines for Americans*:

Special attention should be given to portion sizes, which have increased significantly over the past two decades (http://hin.nhlbi.nih.gov/portion/index.htm). Though there are no empirical studies to show a causal relationship between increased portion sizes and obesity, there are studies showing that controlling portion sizes helps limit calorie intake, particularly when eating calorie-dense foods....⁷⁵

Portion sizes in this country have increased in both restaurants and the home over the past two decades. In many restaurants, many food and beverage items, such as soft drinks, steaks, and pastries, are now served in portions that are twice or several times as large as the standard serving size defined by the U.S. Food and Drug Administration (FDA). The trend toward larger portion sizes has a powerful economic basis, since large portions provide an important value option for consumers. For foodservice establishments, the actual monetary costs of larger portions can be modest, because the cost of the food itself is modest (on average about 20% of retail costs) relative to labor, packaging, transportation, marketing, and other costs.

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⁷³ B. Wansink, "Environmental Factors that Increase the Food Intake and Consumption Volume of Unknowing Consumers," *Annual Review of Nutrition* 24 (2004): 455-479.

⁷⁴ B.J. Rolls, "The Supersizing of America: Portion Size and the Obesity Epidemic," *Nutrition Today* 38, no. 2 (2003): 42-53; and J.A. Ello-Martin, J.H. Ledikwe, and B.J. Rolls, "The Influence of Food Portion Size and Energy Density on Energy Intake: Implications for Weight Management," *American Journal of Clinical Nutrition* 82 (suppl.) (2005): 236S-241S

⁽suppl.) (2005): 236S-241S.

⁷⁵ U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA), *Dietary Guidelines for Americans 2005* (6th ed.) (Washington, DC: HHS and USDA, 2005).

⁷⁶ U.S. Bureau of the Census, *Statistical Abstract of the United States: 1985*, 114th ed. (Washington, DC: U.S. Bureau of the Census, 1994); U.S. Bureau of the Census, *Statistical Abstract of the United States: 1994*, 105th ed. (Washington, DC: U.S. Bureau of the Census, 1984); J.O. Hill and J.C. Peters, "Environmental Contributions to the Obesity Epidemic," *Science* 280 (1998): 1371-1374; H. Smiciklas-Wright, et al., "Foods Commonly Eaten in the United States, 1989-1991 and 1994-1996: Are Portion Sizes Changing?" *Journal of the American Dietetic Association* 103, no. 1 (2003): 41-47; and L.R. Young and M. Nestle, "The Contribution of Expanding Portion Sizes to the U.S. Obesity Epidemic," *American Journal of Public Health* 92, no. 2 (2002): 246-249.

⁷⁷ M.F. Jacobson and J.G. Hurley, *Restaurant Confidential* (New York, NY: Workman Publishing, 2002).

⁷⁸ B. Wansink and M. Huckabee, "De-Marketing Obesity," *California Management Review* 47, no. 4 (2005): 6-18.

⁷⁹ H. Elitzak, "Calculating the Food Marketing Bill," *Amber Waves*, February 2004: 43.

This trend toward larger portions, affecting both away-from-home and at-home foods, has coincided with increases in the prevalence of obesity. Recent studies indicate that the availability of large portions of food (both meal-related and snack-related) can result in increased caloric intake and therefore can contribute to the growing incidence of obesity. Across a range of different types of foods, the bigger the portion served, the greater is both the weight of food consumed and the calories consumed. Studies conducted in both laboratory and naturalistic settings (e.g., restaurants, cafeterias, and movie theaters) indicate that providing individuals with larger portions of food leads to substantial increases in calorie intake. This effect has been shown for packaged snack foods, foods of amorphous shape such as macaroni and cheese, and foods consumed as a unit such as sandwiches. The effect has also been demonstrated with entrees in a cafeteria and popcorn in a movie theater—even when the popcorn was stale.

The effect of portion size persists beyond a single meal and is sustained from meal to meal. In other words, even when the portion size of all foods served over several days is increased, there is a persistent and significant effect on caloric intake, with no evidence of meal-to-meal adjustment in the consumption of calories.⁸⁷

People generally appear to consume not only more food but also more calories when offered larger portions, and they often report similar ratings of hunger and fullness as those offered smaller portions of the same foods. 88 There is reason to believe, then, that consumers adjust their level of satiety to accommodate greater calorie intake than is needed.

The reasons *why* increased portions can result in greater caloric intake are not yet well understood. One reason may be that people (whether due to visual cues or socialization) tend to eat as much as they can of what they are served, as long as it is palatable; larger portions suggest that larger amounts are "normal" or "appropriate." Another reason may be that people tend to

⁸⁰ Young and Nestle, "The Contribution of Expanding Portion Sizes," 2002.

⁸¹ N. Diliberti, et al., "Increased Portion Size Leads to Increased Energy Intake in a Restaurant Meal," *Obesity Research* 12 (2004): 562-568; Ello-Martin, Ledikwe, and Rolls, "The Influence of Food Portion Size," 2005; B.J. Rolls, E.L. Morris, and L.S. Roe, "Portion Size of Food Affects Energy Intake in Normal-Weight and Overweight Men and Women," *American Journal of Clinical Nutrition* 76 (2002): 1207-1213; B.J. Rolls, et al., "Increasing the Portion Size of a Packaged Snack Increases Energy Intake in Men and Women," *Appetite* 42 (2004): 63-69; and B. Wansink and S. Park, "At the Movies: How External Cues and Perceived Taste Impact Consumption Volume," *Food Quality and Preference* 12, no. 1 (2001): 69-74.

⁸² Rolls, et al., "Increasing the Portion Size of a Packaged Snack," 2004.

⁸³ Rolls, Morris, and Roe, "Portion Size of Food Affects Energy Intake," 2002.

⁸⁴ B.J. Rolls, et al., "Increasing the Portion Size of a Sandwich Increases Energy Intake," *Journal of the American Dietetic Association* 104 (2004): 367-372.

⁸⁵ Diliberti, et al. "Increased Portion Size Leads to Increased Energy Intake," 2004.

⁸⁶ B. Wansink and J. Kim, "Bad Popcorn in Big Buckets: Portion Size Can Influence Intake as Much as Taste," *Journal of Nutrition Education and Behavior* 37, no. 5 (2005): 242-245.

⁸⁷ B.J. Rolls, L.S. Roe, and J. Meengs, "Larger Portion Sizes Lead to Sustained Increase in Energy Intake over Two Days," *Journal of the American Dietetic Association*, in press (April 2006).

⁸⁸ Rolls, Morris, and Roe, "Portion Size of Food Affects Energy Intake," 2002; and Ello-Martin, Ledikwe, and Rolls, "The Influence of Food Portion Size," 2005.

⁸⁹ Wansink, "Environmental Factors that Increase the Volume of Food Intake," 2004.

eat in units—that is, they tend to consume (or try to consume) all of a pre-portioned food, such as a sandwich, cookie, or beverage. 90

Also, consumers are often unable to assess the amount they are eating, even when there is information available about appropriate serving sizes. Gauging appropriate servings is difficult enough that people are often unable to tell the differences in portion size when offered different sizes of the same foods on different days. Survey data and experimental findings indicate that many people let the server determine an appropriate portion and eat accordingly, so that the bigger the portion the more they consume.

The ability to accurately determine appropriate amounts of food to eat is important, but other than piecemeal estimation strategies, ⁹⁴ there is little research to suggest which methods would be most successful in helping people estimate appropriate serving sizes. One study concluded that the characteristics of people (e.g., gender, age, body weight, level of education) cause differences in the way they estimate portion size, and error in estimating becomes greater as portions increase. ⁹⁵ In addition, physiologic satiety cues (i.e., feelings of fullness) are readily overridden by food cues, such as large portions, easy access, and the sensory attractiveness of food. ⁹⁶

Children may lose the ability to adjust their food intake to meet their energy needs when given larger portion sizes. ⁹⁷ However, the intake of younger children (age 3 or younger) tends to be relatively unaffected by environmental cues such as portion size. ⁹⁸ Still, portion size is the single predictor responsible for the greatest amount of variance in daily energy intake for children generally. ⁹⁹ Children taught to focus on their own fullness tend to adjust their intake better than children rewarded for eating whatever is set before them—i.e., cleaning their plates. ¹⁰⁰

P.S. Siegel, "The Completion Compulsion in Human Eating," *Psychological Reports* 3 (1957): 15-16; and J.A. Ello-Martin, et al., "Increasing the Portion Size of a Unit Food Increases Energy Intake," *Appetite* 39 (2002): 86.
 Rolls, Morris, and Roe, "Portion Size of Food Affects Energy Intake," 2002; L.R. Young and M.S. Nestle,

[&]quot;Portion Sizes in Dietary Assessment: Issues and Policy Implications," *Nutrition Review* 53 (1995): 149-158; and Ello-Martin, et al., "Increasing the Portion Size of a Unit Food," 2002.

⁹² Diliberti, et al. "Increased Portion Size Leads to Increased Energy Intake," 2004.

⁹³ American Institute for Cancer Research, *Awareness and Action: AICR Surveys on Portion Size, Nutrition, and Cancer Risk* (Washington, DC: AICR, 2003). See www.aicr.org/site/DocServer/ awarenessandaction 03conf.pdf?docID=106.

⁹⁴ P. Chandon and B. Wansink, "Obesity and the Calorie Underestimation Bias: A Psychophysical Model of Fast-Food Meal Size Estimation," *Journal of Marketing Research*, forthcoming (2007).

⁹⁵ L.R. Young and M. Nestle, "Variation in Perceptions of a 'Medium' Food Portion: Implications for Dietary Guidance," *Journal of the American Dietetic Association* 98 (1998): 458-459.

⁹⁶ V.E. Pudel and M. Oetting, "Eating in the Laboratory: Behavioural Aspects of the Positive Energy Balance," *International Journal of Obesity* 1 (1977): 369-386.

⁹⁷ J.O. Fisher, B.J. Rolls, and L.L. Birch, "Children's Bite Size and Intake of an Entrée Are Greater with Large Portions than with Age-Appropriate or Self-Selected Portions," *American Journal of Clinical Nutrition* 77, no. 5 (2003): 1164-1170; B.J. Rolls, D. Engell, and L.L. Birch, "Serving Portion Size Influences 5-Year-Old but Not 3-Year-Old Children's Food Intakes," *Journal of the American Dietetic Association* 1000 (2000): 232-234; and K.L. McConahy, et al., "Food Portions Are Positively Related to Energy Intake and Body Weight in Early Childhood," *Journal of Pediatrics* 140, no. 3 (2002): 340-347.

⁹⁸ Rolls, Engell, and Birch, "Serving Portion Size Influences 5-Year Old," 2000.

⁹⁹ K.L. McConahy, et al., "Portion Size of Common Foods Predicts Energy Intake among Preschool-Aged Children," *Journal of the American Dietetic Association* 104, no. 6 (2004): 975-979.

¹⁰⁰ L.L. Birch, et al., "Clean Up Your Plate: Effects of Child Feeding Practices on the Conditioning of Meal Size," *Learning and Motivation* 18 (1987): 301-317.

In summary, then, research indicates that portion size influences how many calories a person consumes, and individuals are often unable to accurately assess how much they are eating. Because increased portions are pervasive in our culture, from restaurants to supermarkets to vending machines, it is important to address the issue of portion size to help people choose appropriate amounts of food, given their energy needs.

Calorie Density and Caloric Intake

The Dietary Guidelines indicate that managing portion size is particularly important when consuming calorie-dense foods. ¹⁰¹ While further studies are needed to determine the average calorie density of meals among different sub-sectors of away-from-home meal providers, the fact is that many foods available in large portions in foodservice settings are higher in calorie density than the overall U.S. diet. ¹⁰²

When the palatability of the available foods is similar, individuals appear to eat a consistent weight of food despite variations in calorie density. ¹⁰³ In general, therefore, the lower the calorie density, the lower the calorie intake. In one study, for example, when the calorie density of the available foods was reduced by 30% on the second day, participants decreased their daily energy intake by 30%. ¹⁰⁴

Of all the components of foods, water has the greatest influence on calorie density, since it adds substantial weight without adding calories. Fat, because of its high energy content (9 kcal/g), has a greater influence on the calorie density of a food than either carbohydrate or protein (4 kcal/g). Not all high-fat foods have a high calorie density; the incorporation of water lowers the calorie density of even high-fat foods.

For some foods, reducing the calorie density—either by decreasing the fat content or by increasing water-rich components such as vegetables—may affect the taste and therefore acceptability to the eater. Laboratory-based studies indicate that for other foods, reductions in calorie density do not affect acceptability. ¹⁰⁶

¹⁰¹ HHS and USDA, *Dietary Guidelines for Americans*, 2005.

¹⁰² A.M. Prentice and S.A. Jebb, "Fast Foods, Energy Density, and Obesity: A Possible Mechanistic Link," *Obesity Review* 4 (2003): 187-194; J.H. Ledikwe, et al., "Dietary Energy Density Determined by Eight Calculation Methods in a Nationally Representative United States Population," *Journal of Nutrition* 135 (2005): 274-278; and C.B. Ebbeling, et al., "Compensation for Energy Intake from Fast Food among Overweight and Lean Adolescents," *Journal of the American Medical Association* 291 (2004): 2828-2833.

¹⁰³ E.A. Bell, et al., "Energy Density of Foods Affects Energy Intake in Normal-Weight Women," *American Journal of Clinical Nutrition* 67 (1998): 412-420; and B.J. Rolls, L.S. Roe, and J.S. Meengs, "Reductions in Portion Size and Energy Density of Foods are Additive and Lead to Sustained Decreases in Energy Intake over Two Days," *American Journal of Clinical Nutrition* 83 (2006): 11-17.

¹⁰⁴ Bell, et al., "Energy Density of Foods Affects Energy Intake," 1998.

¹⁰⁵ Ello-Martin, Ledikwe, and Rolls, "The Influence of Food Portion Size," 2005; and B.J. Rolls, A. Drewnowski, and J.H. Ledikwe, "Changing the Energy Density of the Diet as a Strategy for Weight Management," *Journal of the American Dietetic Association* 105 (2005): 98-103.

¹⁰⁶ Ello-Martin, Ledikwe, and Rolls, "The Influence of Food Portion Size," 2005.

Calorie-dense foods are often the lowest-cost dietary option for the consumer. The calorie density of the diet tends to be linked inversely to diet cost; low-cost diets are frequently energy-dense but nutrient poor. 107

Reducing the calorie density of the diet appears to be an effective approach for weight management; controlled studies have found an association between a reduced calorie-density diet and reduced calorie intake and body weight. Increasing intake of water-rich (low-calorie-dense) foods, such as fruits and vegetables, while restricting portions of high-calorie-dense foods, can lead to successful weight loss. Also, participants eating less-calorie-dense diets generally report less hunger than dieters who simply reduce their fat intake.

Since both the portion size and the calorie density of foods can affect energy intake, a critical issue is to determine how these influences work together. In one study, 25% reductions in both portion size and calorie density together had a substantial impact on calorie intake, with no increase in reported hunger. Because reductions in portion size and calorie density can add together to provide a bigger effect on calorie intake, a promising approach is to make small changes in both to commonly consumed foods. Since it was also found that reductions in the calorie density of foods were both more effective in reducing energy intake and less noticeable than reductions in portion size, decreasing calorie density while maintaining portion sizes may also provide an acceptable and productive approach to help moderate energy intake. Also, for calorie-dense foods it is particularly important to provide information that could help consumers select appropriate portions.

Palatability, Variety, and Caloric Intake

A greater variety of appealing (and immediately available) foods can contribute to the overconsumption of calories. ¹¹¹ In general, people tend to eat more of foods that taste good to them. The greater the palatability of a food, the greater is the intake of that food at a meal. ¹¹² While the palatability of a particular food declines as consumption of it increases, the appeal of other foods (with different sensory properties) available at the same eating occasion is not affected. Individuals thus tend to consume more food when the variety (i.e., the number of foods

¹⁰⁷ E. Andrieu, N. Darmon, and A. Drewnowski, "Low-Cost Diets: More Energy, Fewer Nutrients," *European Journal of Clinical Nutrition* 60 (2006): 434-436; and A. Drewnowski and N. Darmon, "The Economics of Obesity: Dietary Energy Density and Energy Cost," *American Journal of Clinical Nutrition* 82 (2005): 265S-273S.

¹⁰⁸ B.J. Rolls, J.A. Ello-Martin, and B.C. Tohill, "What Can Intervention Studies Tell Us about the Relationship between Fruit and Vegetable Consumption and Weight Management?" *Nutrition Reviews* 62 (2004): 1-17; B. Rolls, et al., "Provision of Foods Differing in Energy Density Affects Long-Term Weight Loss," *Obesity Research* 13 (2005): 1052-1060; and R.L. Weinsier, et al., "Dietary Management of Obesity: Evaluation of the Time-Energy Displacement Diet in Terms of Its Efficacy and Nutritional Adequacy for Long-Term Weight Control," *British Journal of Nutrition* 47 (1982): 367-379.

¹⁰⁹ Rolls, Roe, and Meengs, "Reductions in Portion Size and Energy Density," 2006.

¹¹⁰ Ello-Martin, Ledikwe, and Rolls, "The Influence of Food Portion Size," 2005; and Rolls, Drewnowski, and Ledikwe, "Changing the Energy Density of the Diet," 2005.

¹¹¹ B.J. Rolls, "Sensory-Specific Satiety," *Nutrition Reviews* 44 (1986): 93-101; B.J. Rolls, "Sensory-Specific Satiety and Variety in the Meal," in H. L. Meiselman (ed.), *Dimensions of the Meal: The Science, Culture, Business and Art of Eating* (Gaithersburg, MD: Aspen Publishers, 2000): 107-116; B.J. Rolls, P.M. van Duijvenvoorde, and E.T. Rolls, "Pleasantness Changes and Food Intake in a Varied Four-Course Meal," *Appetite* 5 (1984): 337-348.

¹¹² L.B. Sorensen, et al., "Effect of Sensory Perception of Foods on Appetite and Food Intake: A Review of Studies on Humans," *International Journal of Obesity* 27 (2003): 1152-1166.

with different sensory properties) available at a meal is increased. As one food begins to lose its appeal, consumers can move on to other choices.

Since most controlled studies of variety and intake have used palatable, energy-dense foods, the results generally show an increase in caloric intake as variety is increased. It is possible, however, that the effect of food variety could be combined with that of calorie density in a strategy to decrease caloric intake. In at least two recent studies, a greater variety of low-calorie-dense foods and less variety of high-calorie-dense foods was associated with lower caloric intakes, lower body fat, and greater weight loss than diets with a greater variety of high-energy-dense foods and less variety of low-energy-dense foods.

Other Factors in Consumers' Immediate Environment

In addition to the cues described above, other factors add to the effect of portion size, causing people to eat more than they need, particularly in a restaurant setting. For example, dining out can affect calorie intake due to the convivial atmosphere, a tendency to choose foods with high energy densities, and in the context of the disinhibiting effects of alcohol consumption. ¹¹⁶

Some emerging research suggests that other environmental factors may also influence consumers' perceptions of what an appropriate amount to eat is in a certain situation, or may bias or confuse consumers' estimates of how much they have eaten. Examples include: socializing while eating; the visibility or ready availability of food; and distractions (such as reading or watching television while eating). Recent studies also suggest that the size and shape of packaging (including bowls, plates, and glasses) may have a similar effect on the volume of food intake. Studies manipulating package sizes have shown that serving oneself from larger

¹¹³ Rolls, van Duijvenvoorde, and Rolls, "Pleasantness Changes and Food Intake," 1984.

¹¹⁴ B.J. Rolls, et al., "Sensory Specific Satiety in Man," *Physiology and Behavior* 27 (1981): 137-142; Rolls, van Duijvenvoorde, and Rolls, "Pleasantness Changes and Food Intake," 1984; and B.J. Rolls, E.A. Rowe, and E.T. Rolls, "How Sensory Properties of Foods Affect Human Feeding Behavior," *Physiology and Behavior* 29 (1982): 409-417.

¹¹⁵ M.A. McCrory, et al., "Dietary Variety within Food Groups: Association with Energy Intake and Body Fatness in Men and Women," *American Journal of Clinical Nutrition* 69 (1999): 440-447; and H.A. Raynor, et al., "Relationship between Changes in Food Group Variety, Dietary Intake, and Weight during Obesity Treatment," *International Journal of Obesity* 28 (2004): 813-820.

¹¹⁶ Rolls, "The Supersizing of America," 2003.

Wansink, "Environmental Factors that Increase the Food Intake," 2004.

¹¹⁸ R. Bell and P.L. Pliner, "Time to Eat: The Relationship between the Number of People Eating and Meal Duration in Three Lunch Settings," *Appetite* 41 (2003): 215-18; J.M. de Castro, "Eating Behavior: Lessons from the Real World of Humans," *Ingestive Behavior and Obesity* 16 (2000): 800-13; and J.M. de Castro and E. Brewer, "The Amount Eaten in Meals by Humans is a Power Function of the Number of People Present," *Physiological Behavior* 51 (1992): 121-25.

¹¹⁹ J.E. Painter, et al., "How Visibility and Convenience Influence Candy Consumption," *Appetite* 38 (2002): 237-238; A.W. Meyers, et al., "Food Accessibility and Food Choice," *Archives of General Psychiatry* 37 (1980): 1133-1135; and N.D. Volkow, et al., "Nonhedonic' Food Motivation in Humans Involves Dopamine in the Dorsal Striatum and Methylphenidate Amplifies This Effect," *Synapse* 44 (2002): 175-80.

¹²⁰ Wansink, "Environmental Factors that Increase the Food Intake," 2004.

¹²¹ Ibid.; B. Wansink and K. Van Ittersum, "Bottoms Up! Peripheral Cues and Consumption Volume," *Journal of Consumer Research* 30 (2003): 311-19; B. Wansink and K. Van Ittersum, "Illusive Consumption Behavior and the DelBoeuf Illusion: Are the Eyes Really Bigger than the Stomach?" under review; and B. Wansink, "Can Package Size Accelerate Usage Volume?" *Journal of Marketing* 60, no. 30 (1996): 1-14.

packages increases the amount served by 18-48%. Also, individuals who inadvertently overserve themselves—and therefore eat more—because of the biasing influence of large serving bowls often do not necessarily report feeling fuller or less hungry than those using smaller bowls. 123

Since consumers' immediate environment influences not only what they eat but how many calories they consume, small structural changes in calorie density, portion size, package design, plate or glass size or shape, and other factors can help reduce the *unknowing* overconsumption of calories. The Forum's recommendations for assisting consumers of away-from-home foods through such environmental adjustments are detailed later in this chapter and in Chapter 3.

Existing Education and Marketing Efforts

Government agencies, nonprofit entities, and private-sector companies all seek to influence the food choices consumers make. Several dozen existing federal programs and numerous civic-sector programs actively seek to influence consumer behavior and attitudes regarding food; many of these programs are relevant to obesity prevention in the area of away-from-home foods. Also, as with any large industry sector, the away-from-home foods sector not only responds to consumer demand but also seeks to shape and influence that demand through what they offer, how they offer it, and how they market and advertise it. Current social marketing efforts and commercial marketing activity are summarized in this section.

Social Marketing and Education

Social marketing programs—whether administered by government entities, civic-sector organizations, or, occasionally, private-sector organizations—deliver messages that aim to bring about voluntary behavior change, often within specific demographic audiences. Social marketing programs typically seek to improve personal or societal welfare—for example, by promoting healthy eating, active living, avoidance of illegal drug use, or proper use of seat belts.

The federal government operates a number of social marketing and public education programs that attempt to influence consumer behavior related to nutrition and food consumption. While some are national in scope, many are relatively small programs (in terms of audience and resources), and most do not benefit from nor rely on any extensive media coverage or promotion. Many of the federal government's campaigns consist of printed or web-based materials provided in language and detail specific to the intended audience (e.g., consumers, health professionals). Two of the larger programs are (1) the Dietary Guidelines for Americans, a joint project of the U.S. Department of Health and Human Services (HHS) and the U.S. Department of Agriculture (USDA), and (2) the "5 A Day" program housed at the Centers for Disease Control and Prevention (CDC) and conducted in collaboration with several national partners.

The Keystone Forum on Away-From-Home Foods—Final Report

¹²² Wansink, "Can Package Size Accelerate Usage Volume?" 1996.

¹²³ B. Wansink and M.M. Cheney, "Super Bowls: Serving Bowl Size and Food Consumption," *Journal of the American Medical Association* 293 (2005): 1727-1728.

The civic sector also uses social marketing as part of its obesity-prevention efforts. Most campaigns have been relatively small-scale efforts backed up by local events and grassroots education. In addition, many campaigns have focused on promoting healthful behaviors generally, such as being physically active, as opposed to messages regarding specific food choices. Two exceptions are the Corner Store Project and the 1% Or Less campaign, both of which specifically target food choices.

Private-sector organizations also fund a variety of efforts relevant to weight management. Several programs focus on active living and/or healthy eating, such as America on the Move and the Everyday Choices campaign. 124 Private-sector programs may focus on specific population groups such as school-aged children, specific settings such as worksites, or specific methods such as nutrition services or physical education.

Appendix D contains an overview of selected current or recent programs undertaken by government agencies and civic organizations in the areas of nutrition/obesity and consumer behavior. (The appendix includes some programs that focus on increased physical activity, which, while outside the scope of the Forum, are listed due to their relevance to obesity prevention.) The relative efficacy of these programs is generally not assessed regularly nor systematically, and no standard process exists for conducting such an assessment. The Forum therefore proposes (later in this chapter, as Recommendation 2.5) a comprehensive survey of the federal government's social marketing and education programs that relate to nutrition and obesity prevention.

Forum participants also see a need for more effective social marketing efforts aimed at healthy weight management that are both national in scope and that encompass away-from-home eating. These programs should influence and support behaviors pursuant to obesity prevention. Two specific proposals for launching or enhancing consumer-oriented programs are presented later in this chapter as Recommendations 2.3 and 2.4.

In general, participants believe that such consumer-oriented programs should:

- Increase consumers' awareness of their caloric requirements and the contribution of awayfrom-home foods to their overall caloric intake.
- Challenge the perception that value for the food dollar is based on volume or quantity.
- Clearly communicate and help people put into practice the principles of balance, moderation, and healthful variety within and between food groups.
- Educate consumers about techniques for lowering their caloric intake, including selecting lower-calorie and less-calorie-dense choices such as fruits and vegetables, low-calorie beverages, and other low-calorie meal components; requesting lower-calorie preparation methods; decreasing portion sizes; and making choices between meal components (for example, choosing an appetizer or dessert, but not both).
- Provide consumers with guidance in selecting and consuming portions appropriate to their caloric needs, given their physical activity levels and other considerations.
- Encourage consumers to look for and ask for calorie information regarding away-from-home
- Challenge the perception that healthy foods lack taste or are less satisfying.

¹²⁴ See www.americaonthemove.org and www.everydaychoices.org.

Commercial Marketing

Restaurants spend \$4.4 billion annually on advertising ("measured media"), including magazine, newspaper, outdoor, television, radio, and internet advertising. Television advertising on broadcast and cable networks accounts for 84% of those expenditures. In 2004, the restaurant sector accounted for almost half of all food advertising on broadcast television; the sector spent \$3.12 billion compared to \$3.42 billion spent by other segments of the food and beverage industry. Spending on "unmeasured media"—such as sponsorships, community events, press events, product placements, coupons, viral marketing, e-mail, and text messaging—may account for as much as or more of a restaurant company's marketing budget. Most advertising by restaurants is conducted by the quick-service sector.

Some marketing dollars pay for sponsorships of athletic or social marketing programs. Many of these are noted in the annual reports of major food and restaurant corporations.

Comprehensive marketing data for the entire away-from-home food market are not publicly available. Data are particularly scarce for non-restaurant venues such as on-site contract dining services and prepared food offerings at grocery stores.

Marketing to Children

Each year, companies spend an estimated \$10 billion marketing foods and beverages (including away-from-home foods) to children and youth in the United States. Away-from-home food marketing, as with other marketing aimed at kids, is designed to be highly appealing. Ads directed to children feature fun and adventure and are often colorful, musical, and include cartoon and/or other well-loved spokes-characters. Away-from-home food outlets market their products and brands to children using television advertising, toy giveaways, contests, kids' clubs, celebrities, spokes-characters, school fundraisers, and movie and television show tie-ins and cross-promotions.

The overwhelming majority of food advertisements aimed at children are for foods and beverages high in sugars, fat, and/or salt, such as sugary cereals, sweetened drinks, fast food, candy, and chips. ¹³⁰ Few to no ads are for fruits or vegetables. Fewer than 10% of the ads are for foods low in sugars, fat, and salt. ¹³¹

¹²⁵ Brown, et al., "50th Annual 100 Leading National Advertisers," *Advertising Age*, June 27, 2005.

¹²⁶ Ibid.

¹²⁷ Ibid.

¹²⁸ A.E. Gallo, *Food Advertising in the United States*, Agricultural Information Bulletin #750 (Washington, DC: USDA, 1998).

¹²⁹ Institute of Medicine, *Food Marketing to Children: Threat or Opportunity?* (Washington, DC: National Academies Press, 2006).

¹³⁰ M. Gamble and N. Cotugna, "A Quarter Century of TV Food Advertising Targeted at Children," American Journal of Health Behavior 23 (1999): 361-267; Consumers International, A Spoonful of Sugar: Television Food Advertising Aimed at Children, An International Comparative Survey (London: Consumers International, 1996); and K. Kotz and M. Story, "Food Advertisements During Children's Saturday Morning Television Programming: Are

The World Health Organization, the National Academies' Institute of Medicine (IOM), the Children's Advertising Review Unit (CARU), and others have raised concerns that children are uniquely susceptible to food marketing. For example, CARU, part of the Council of Better Business Bureaus (a self-regulatory agency of the food and advertising industries), states: "Children's limited capacity for evaluating information dictates that advertisers have a special responsibility to protect young children from their own susceptibilities," and that a "child may learn practices from advertising which can affect his or her health and well-being." ¹³² The American Psychological Association concluded that children under eight years of age lack the ability to understand the persuasive intent of commercials. ¹³³ In addition, the IOM found that children as old as 11 years may not activate their defenses against advertising unless explicitly cued to do so. 134

Recently, the Institute of Medicine undertook the most comprehensive review to date of the influence of food marketing on children. The IOM found that television advertising influences children's food and beverage preferences and purchase requests. It also found that television food and beverage advertising influences consumption and is a contributor to less healthful diets, and that television watching is related to obesity in children. Most of the studies that have been conducted on the effects of food marketing to children have assessed the effects of television advertising and have been done regarding children under the age of 12 years. The statistical association between advertisement viewing and obesity is strong. However, the IOM report found that available studies are unable to determine whether television advertising is a direct cause of obesity among children. 135

Marketing is a powerful means of reaching consumers—of raising their awareness and of influencing their interests over time. Both commercial and social marketing, whether aimed at adults or at children, should increasingly promote away-from-home food choices and eating behaviors that are consistent with healthy weight management. Recommendations 2.1 and 2.2 address this proposed shift. Recommendation 2.3 calls for a comprehensive consumer education program to promote low-calorie-dense dietary patterns.

Existing Data-Collection Efforts

In addition to taking action now based on what is already known, as discussed in previous sections of this chapter, Forum participants believe it is important to continually improve the knowledge base regarding consumer behavior and away-from-home foods. Much of what can be

They Consistent with Dietary Recommendations?" Journal of the American Dietetic Association 94 (1994): 1296-

¹³¹ H.L. Taras and M. Gage, "Advertised Foods on Children's Television," Archives of Pediatrics and Adolescent Medicine 149 (1995): 649-642.

¹³² Children's Advertising Review Unit (CARU), Self-Regulatory Guidelines for Children's Advertising (New York: CARU, 2003). See www.caru.org/guidelines/guidelines.pdf.

¹³³ D. Kunkel, et al., Report of the APA Task Force on Advertising and Children (Washington, DC: American Psychological Association, 2004).

¹³⁴ Institute of Medicine, Food Marketing to Children, 2006.

¹³⁵ Ibid.

known about consumer behavior regarding away-from-home foods is proprietary and generally not available to this Forum or to most stakeholders, since consumer data has important competitive value to the private sector and is either unavailable or costly. However, several significant government data-collection efforts exist, and some commercial data are shared publicly on a periodic basis.

Government Efforts

The United States has one of the most comprehensive nutrition monitoring programs in the world, and the data collected serves the needs of people in government, academia, nonprofit organizations, health and nutrition advocates, and the private sector. No consistent data-collection mechanism focuses extensively on the consumption of away-from-home foods, however. Thus, federal efforts have leveraged existing data sources to gather information on consumer behavior related to away-from-home foods. These efforts occur primarily in the form of questions added to existing surveys, or the utilization of data from questions not originally focused on away-from-home foods, but that can be analyzed to provide some insight into consumer behavior on that topic. These surveys examine, for example, the number of times per week that individuals consume meals prepared in a restaurant, the location of food consumption, and how often a parent eats out with their child.

Current and recent efforts to collect national data on consumer behavior related to away-from-home food use include the following.

- The National Health and Nutrition Examination Survey (NHANES), conducted by the CDC
- What We Eat in America, a survey conducted by the USDA
- The Continuing Survey of Food Intakes by Individuals, conducted previously by the USDA, now conducted by the CDC as part of NHANES
- The Health and Diet Survey, conducted by the FDA
- The American Time Use Survey (ATUS), conducted by the Department of Labor
- The Early Childhood Longitudinal Study, conducted by the Department of Education

A brief description of each of these programs can be found in Appendix E.

In addition, through its data development initiative, the USDA's Economic Research Service (ERS) has increased its access to private-sector data on the purchase and consumption of selected away-from-home foods (that is, restaurant, fast food, take-out, etc.). These data will be used by the ERS for analyses that will improve public understanding of the factors that determine the purchase and consumption of away-from-home foods and the nutritional consequences of the consumption of those foods. However, the ERS purchased the data under a one-year agreement; it is uncertain at this time whether the information will be obtained regularly going forward.

Federal partners have made other efforts to improve the publicly available data being collected on away-from-home foods. Beginning in 2003-04, NHANES included questions on where food is obtained (e.g., restaurant or fast food vs. from home) and consumed. In 2005, the ERS added some questions to the NHANES on consumer behavior regarding away-from-home foods. As part of its data development initiative, the ERS is developing a flexible consumer behavior

module that will be added to future NHANES, beginning in 2007. Many of the questions that are planned for inclusion in that module address determinants of consumption of away-from-home foods. NHANES data are made publicly available for analysis by the National Center for Health Statistics at the CDC. It is important to note that the additional NHANES questions are part of a one-time, two-year cycle, and will not in themselves allow for an ongoing stream of data.

The ERS also provided funding to add a Food and Eating Behavior Module to the ATUS in October 2005 and continuing through 2006. This module will address issues of where and when Americans are eating. This effort will support the collection of data on "eating as a secondary activity"—that is, eating while driving, watching TV, and so forth. The module will also collect data on height and weight, making it useful for studying associations between obesity and lifestyle issues such as "dashboard dining." As with the NHANES additions, the new ATUS module, while important, will not provide the continuing data necessary to examine trends over time. Such data gathering would require more funding and support.

Commercial Efforts

Some market research firms systematically track consumer food choice and eating behavior. Two notable examples of syndicated, commercially available information sources—both from The NPD Group—are highlighted here.

The NPD Group is a company that develops and provides sales and marketing information to the food and beverage and foodservice industries. The company's National Eating Trends survey monitors the eating and drinking habits of U.S. consumers by tracking the activities of a nationally representative sample of 2,000 households and approximately 5,000 individuals. Each panelist fills out a 14-day diary capturing both household and individual consumption. Each daily diary includes information about food, beverage, additive, and ingredient consumption. The consumption information captured includes the food, form, flavor, special label code, package type, package form, dish position, appliance used, and preparation methods. In addition, the household demographics—e.g., income, education, employment status, number and age of children, race, and census region—are also captured. On the fifteenth day, individuals record their height and weight, diet status and type of diet, medical conditions, vitamin intake, and exercise behavior, allowing for the ability to compare the respondent's health status with their consumption habits.

NPD's Consumer Reporting of Eating Share Trends (CREST) is a syndicated survey that collects consumer information about commercially prepared meals and snacks. A daily online survey is used for capturing data from a large panel of individuals regarding all meals and snacks purchased the day before, either for immediate consumption from commercial restaurants and other retail channels such as convenience stores, supermarkets, and mass merchandisers, or for onsite eating. The online panel is a group of 3,000 adults and 500 teenagers that is demographically and geographically balanced to represent the U.S. population. The CREST survey captures many aspects about a consumer's visit to foodservice establishments, including the outlet visited, foods and beverages purchased, the day of the week, average check size, prior activities, demographics, customer satisfaction, and attitudinal information.

A Coordinated Research Agenda

Forum participants believe that a coordinated research agenda is needed to augment, and continually improve upon, the existing knowledge base that supports efforts to help consumers manage their caloric intake when choosing and consuming away-from-home foods and beverages.

While valuable data can be mined from the existing government surveys, those surveys currently do not provide information on what drives consumer behaviors towards certain products and eating patterns. In addition, the away-from-home food questions generally do not have an ongoing commitment of funds, nor is there a dedicated survey to gather these data. In some cases, the data have been collected but are not available to the public as a precaution to protect the confidentiality of survey participants. Syndicated commercial data could be used to complement current government efforts and provide additional insight into consumer behavior.

Better and more timely information is needed regarding: the choices consumers are making regarding foodservice venues and foods, the values and motivations driving those choices, the factors that motivate changes in behaviors and attitudes, the potential value of nutrition information and other specific interventions, and the best ways to promote changes in products or menus that are relevant to weight management.

A stronger knowledge base in this area will assist with the following.

- Providing policy and program officials with the information necessary to develop and evaluate public efforts to improve diet and health as they relate to the away-from-home food sector
- Better assessment of what messages and messaging strategies might serve as the foundation for campaigns aimed at educating and motivating consumers to make lower-calorie choices
- Better ways to address messages to household decision-makers
- Better understanding of the relative role of away-from-home foods (and how, when, and where people consume them) in the obesity problem
- Developing effective means of stimulating alternative buying and eating behaviors (e.g., testing lower-calorie—or less-calorie-dense—fare in foodservice establishments)

The Forum's proposals regarding a coordinated research agenda are outlined in Recommendations 2.6 and 2.7. A list of questions that should be addressed through further research and analysis, as well as criteria to guide the design of the needed efforts, is included as Appendix F.

The Forum's Recommendations

In this section, Keystone Forum participants offer recommendations on commercial and social marketing, educational and nutrition promotion efforts, and the need for an enhanced research agenda.

Recommendation 2.1

Shift the emphasis of marketing: The marketing of lower-calorie and less-calorie-dense foods should increase, accompanied by a reduction in marketing that highlights higher-calorie (or calorie-dense) foods or encourages large portions.

Companies, government, health organizations, and others should expand and align marketing initiatives (both commercial and social) that help consumers to manage their calorie intake. Foodservice companies and venues should use their full range of creativity and resources to promote food choices and eating behaviors that are consistent with healthy weight management.

In addition, companies, government, health organizations, and others should conduct market research to determine:

- how best to market low-calorie and less-calorie-dense menu options to different populations in ways that assist consumers with weight management efforts, and
- how to shift the prevailing value proposition away from large portions, and how best to market more appropriate portion sizes to different populations.

Recommendation 2.2

Update marketing standards: Industry, government, health and nutrition experts, consumer representatives, and other stakeholders should work together to review and update standards for marketing away-from-home foods to children.

The Children's Advertising Review Unit could work with key stakeholders from the public, private, and civic sectors to review and update its standards for marketing to children, including the marketing of away-from-home foods. CARU, which is funded by members of industry, maintains self-regulatory guidelines for children's advertising, and as of this writing has announced an extensive and consultative review of those guidelines.

Recommendation 2.3

Promote low-calorie-dense dietary patterns: Strengthen and/or create education and promotion programs regarding away-from-home foods that promote the consumption of fruits, vegetables, no- and low-fat milk and milk products, whole grains, and foods low in saturated fats and trans-fatty acids, as recommended by the 2005 Dietary Guidelines for Americans.

The 2005 Dietary Guidelines encourage increased intakes of fruits, vegetables, fat-free or low-fat milk and milk products, and whole grains; the Guidelines also recommend limiting intake of saturated fats and trans-fatty acids. ¹³⁶ These strategies can help individuals effectively manage

The Keystone Forum on Away-From-Home Foods—Final Report

¹³⁶ HHS and USDA, *Dietary Guidelines for Americans*, 2005.

caloric intake and thus help maintain healthy weight. ¹³⁷ The recommended foods are generally low in calorie density (or lower in calories than the products they presumably replace or compete with), and so have an important role to play in healthy weight management. ¹³⁸ While the strength of the evidence linking increased intake of each of these foods to reduced risk of obesity is variable, they may help to decrease overall caloric intake while increasing nutrient intake if they are consumed in appropriate quantities and displace higher-calorie foods.

Fruits and vegetables are a relatively low-calorie-dense food source, for example, and have been shown to be efficacious in regard to satiation and reductions in calorie intake. While studies examining the relationship of whole grain consumption to weight management and body mass index have yielded inconsistent findings, some studies do suggest that whole grains can play a role in healthy weight management. ¹³⁹

While unsaturated fats can be part of a healthful diet, the Dietary Guidelines indicate that individuals should monitor the total amount of fat they consume. Very high intake of total fat (greater than 35% of calories) generally increases saturated fat intake and makes it more difficult to avoid consuming excess calories. ¹⁴⁰

Programs that promote low-calorie-dense dietary patterns should thus be strengthened or created, with evaluation components, to increase consumer demand for the food groups encouraged by the Guidelines, so that consumers will begin to expect and desire more of these foods in their away-from-home eating experiences.

The increased promotion of fruits and vegetables could include the following measures.

- The national 5 A Day for Better Health program could be significantly expanded and strengthened. The program could include a large-scale social marketing campaign to promote fruit and vegetable intake.
- The USDA could create a federal marketing matching program for promoting fruits and vegetables.
- Federally sponsored consumer research could be undertaken to develop behavior change strategies for closing the gap between recommended intakes and current consumption.

The Keystone Forum on Away-From-Home Foods—Final Report

¹³⁷ The *2005 Dietary Guidelines Advisory Committee Report* reviews the evidence linking these encouraged food groups to healthy weight management (see www.health.gov/DietaryGuidelines/dga2005/report/HTML/D6_SelectedFood.htm), and explores the relationship between saturated fat intake and caloric intake (see www.health.gov/DietaryGuidelines/dga2005/report/HTML/D4_Fats.htm). 2005 Dietary Guidelines Advisory Committee, *2005 Dietary Guidelines Advisory Committee Report* (Washington, DC: USDA, 2004).

¹³⁸ Most fruits and vegetables, for example, are low in calorie density because of their high water and fiber content and their low fat content. The water and fiber content of many vegetables and fruits is well documented. The USDA's website on food composition (www.nal.usda.gov/fnic/foodcomp) lists water, fiber, and many other food components (including calories) for hundreds of vegetables and fruits. In efforts to manage caloric intake, fruits and vegetables can be good substitutes for foods high in calorie density. Also, their consumption is associated with decreased cancer and cardiovascular disease.

¹³⁹ 2005 Dietary Guidelines Advisory Committee, "Section 6: Selected Food Groups," *2005 Dietary Guidelines Advisory Committee Report* (Washington, DC: USDA, 2004). See www.health.gov/DietaryGuidelines/dga2005/report/HTML/D6 SelectedFood.htm.

¹⁴⁰ 2005 Dietary Guidelines Advisory Committee, "Chapter 6: Fats," *2005 Dietary Guidelines Advisory Committee Report* (Washington, DC: USDA, 2004). See www.health.gov/dietaryguidelines/dga2005/document/html/chapter6.htm.

The increased promotion of no- and low-fat milk and milk products could include the following measures.

• The Milk Matters program at the National Institute of Child Health and Human Development, as well as the Powerful Bones, Powerful Girls program at the CDC, could be significantly expanded and strengthened to build skills for selecting foods and beverages away from home. The programs could include a large-scale social marketing campaign to promote the intake of three daily servings of low-fat and nonfat milk and milk products, consistent with the Dietary Guidelines.

Recommendation 2.4

Promote enhanced "lifestyle education" programs: Use a combination of social marketing campaigns and consumer education programs to provide "healthy lifestyle" education to help individuals eat more healthfully in today's food environment. Existing campaigns and programs could be enhanced or, as necessary, new ones could be created.

With numerous changes in the food environment, Americans' lifestyles, and schools, many Americans lack the knowledge needed to plan and prepare and/or buy nutritious meals with appropriate levels of calories. Although the Keystone Forum focused on away-from-home foods, participants believe that lifestyle education programs should equip consumers to make informed decisions across the whole spectrum of points of purchase, preparation, and consumption.

Lifestyle education programs could include both social marketing campaigns and new or enhanced curricula and programs in schools and other settings (e.g., parenting courses, workplaces, senior centers). Both the campaigns and programs in various sectors should aim to help individuals understand how to make decisions within the food environment healthfully—i.e., how to navigate the wide range of away-from-home food choices available in today's often harried, time-pressed, convenience-driven world. It could also teach the convenient, economical preparation of low-calorie and less-calorie-dense foods.

Social marketing campaigns should focus on those areas with the most supporting evidence and strongest justification for action. For example, a campaign could seek to change the social value proposition of "more food" to "better-quality food," and/or to promote the concept of energy balance—i.e., balancing caloric intake with energy expenditure.

Recommendation 2.5

Review the effectiveness of existing programs: The HHS and USDA should, in partnership together, coordinate a comprehensive survey and analysis of existing government-sponsored education and social marketing campaigns related to managing weight gain and reducing obesity in the context of away-from-home foods.

Numerous public-, private-, and civic-sector efforts exist to educate consumers broadly about energy balance and how to eat to manage weight gain and obesity. The effectiveness, consistency, and broad impact of these programs, however, are not well known. In addition, no systematic, comprehensive survey of the federal government's social marketing and education programs has been conducted to analyze their consistency, compare their targeted audiences, assess their relative effectiveness, and examine how they could work together.

With decreasing available federal dollars and an increasing problem with obesity and weight gain among both children and adults, the federal government must be efficient and effective with its resources. While numerous consumer-oriented programs may provide "experiments" in how best to reach consumers and positively affect their behavior, little learning will be done across programs and agencies without a thorough evaluation of each program and a more systematic look at such efforts. At present, no widely agreed-upon method exists for analyzing individual efforts and measuring their effectiveness.

Therefore, with HHS and USDA as the coordinators and conveners, key federal agencies should pool resources to sponsor a systematic survey and analysis of education and social marketing campaigns directed at consumers who are trying to manage their weight gain and obesity. Individual agencies should be responsible for analyzing the programs they administer. A standard evaluation tool should be developed for assessing the relative success of each program in helping consumers with healthy weight management.

Though the Forum's scope includes only the away-from-home foods sector, the proposed assessment effort should encompass government-sponsored education programs relating to the entire food environment. In addition to the types of programs characterized in this chapter, for example, consideration should be given to existing food-stamp-related nutrition education efforts. These efforts are included in calculations of how much is spent on nutrition education, they represent a source of funds for providing such information, and they are infrequently studied.

The analysis should seek to identify the target audiences (and any key audiences that have been missed), the kinds of programs implemented, and their effectiveness against criteria developed by the study team, such as ease of understanding by consumers, consumers converting that understanding to action, and costs. Finally, the analysis should offer recommendations for how to streamline government efforts to use resources more efficiently, increase the frequency and consistency of messages, and ultimately, more effectively influence consumer behavior.

Although this recommendation is aimed at federal government agencies, such a review might include an analysis of state-sponsored programs as well as private and nonprofit efforts.

Recommendation 2.6

Improve government access to data on consumer behavior and attitudes: Federal agencies should act immediately to increase the access of government researchers and policymakers to syndicated commercial databases. Key agencies should establish recurring line items in their

respective budgets, thereby ensuring continual and timely access to the needed commercial data sets.

No means presently exists for government to gather and analyze comprehensive data at a national level in the necessary detail, let alone for applying such data in a systematic and coordinated fashion to obesity prevention strategies. Some important efforts are underway, as noted earlier in this section, but much more needs to be done.

Government agencies, civic-sector organizations (such as medical associations and voluntary health organizations), academic researchers, and many foodservice operators lack timely, comprehensive information about consumer motivation and behavior in the away-from-home market. The information that is currently available frequently lags several years behind current societal and market conditions, and lacks needed detail regarding the away-from-home market and specific population groups. Decision-makers and stakeholders need to know much more about what choices consumers are making, what factors determine those choices, and what strategies would help more consumers to make choices consistent with healthy energy intakes.

Therefore, key agencies (e.g., the CDC, FDA, ERS, and the USDA's Center for Nutrition Policy and Promotion) should coordinate needs and resources in order to purchase relevant commercial data sets from syndicated research organizations. Interagency collaboration is needed to ensure adequate funds for an initial purchase of such data sets, to maximize the value of the investment, to promote coordinated policies and programs that result from an analysis of the data, and to encourage the widest possible access to the data in the short term. Going forward, a stable and enduring implementation system is necessary so as to produce trended data over time, creating a framework for understanding changes rather than relying on a snapshot that will quickly lose relevance.

The cost of generating new (and timely) data on the scale needed, whether through new or existing national survey mechanisms, would be prohibitive—and also cost-ineffective, given that much of the data is already being collected by other parties. Significant expansion of existing government mechanisms would necessitate a new employee base, as well as the mobilization of millions of dollars on a recurring basis. Therefore, collaborative purchase of syndicated data is the most cost-effective strategy. (Some participants noted that federal agencies, even working together, should not be expected to accommodate the cost of purchase at current resource levels, particularly when some key agencies are experiencing significant budget reductions.)

Recommendation 2.7

Ensure public availability of information: A means must be developed for continually improving the publicly available knowledge base regarding consumer interests, attitudes, and behaviors regarding away-from-home foods.

Government access to commercial data sets, while very important, is generally accompanied by nondisclosure terms that limit the ways in which the data can directly inform public conversation, and/or that limit analysis by stakeholders outside the federal government. Such

proprietary data restrictions are similar to standard restrictions on confidential data and intellectual property. However, a widely accessible knowledge base is ultimately essential to enable optimal contributions from all parties to the goal of obesity prevention in the area of away-from-home foods. A broad range of stakeholders—including federal, state, local, and tribal governments, smaller industry actors, academic research centers, think tanks, voluntary health organizations, consumer and patient advocacy organizations, medical professionals, educators, and community-serving organizations—have important roles to play in supporting weight management through messages, food products, menu development, policies, and wide-reaching programs to educate and motivate consumers.

Also, while it may be possible to negotiate arrangements whereby commercial data can be shared more widely, there still will be a need to supplement that information flow periodically with qualitative methods such as focus groups, surveys, and town tests.

A collaborative research agenda could thus be developed to focus on consumer behavior and attitudes in the area of away-from-home foods. The feasibility of public-private partnerships for carrying out this effort could be explored, with assistance from philanthropic institutions and in consultation with a diversity of stakeholders. Alternatively, the scope of existing data-gathering initiatives such as NHANES could be expanded to provide more extensive and contemporaneous detail regarding behaviors and attitudes regarding away-from-home foods, both nationwide and within key demographic groups. Data should not only be collected, but it should be analyzed and shared with the public, policymakers, health professionals, and other interested stakeholders.

It is unclear how funds on the required scale would be mobilized to implement this recommendation—especially to allow the research and data acquisition to occur in a centrally coordinated fashion and on a regular, timely basis. Large foodservice companies may have limited incentive to contribute, or even participate, since consumer research data has competitive value; a clear value proposition for business participation must therefore be developed.

Also, if the initiative necessitates a completely new research mechanism (as opposed to augmenting an existing program), it is not clear what type of organization would administer the effort. Speculatively, a partnership that is jointly funded and guided by government agencies, key trade associations, and private foundations, and that is advised actively by a range of independent researchers and other stakeholders, might be developed over time.

Chapter 3 Increasing the Availability of Lower-Calorie Products, Menu Items, and Meals

The foodservice industry faces a number of challenges in its efforts to provide menu items and meals that help consumers effectively manage their calorie intakes and thus maintain healthy weight. These challenges can be viewed as opportunities for the industry to take a proactive role in combating the national problem of overweight and obesity. With this in mind, Keystone Forum participants sought to offer the foodservice industry some achievable, action-oriented strategies, including bold and innovative approaches (in which taste was a non-negotiable "must"), with regard to products, menu items, and meal choices, to assist consumers with managing calorie intake.

Forum participants sought to create recommendations and operational tips that are practical to implement. To address the Forum's goal of reducing obesity, the recommendations focus on manipulating the calorie content, including the calorie density, of menu items and meals through several strategies: providing appropriate portion sizes, plate composition, menu pairing, and beverage options; increasing fruits and vegetables; reducing total fat content; and decreasing the use of ingredients that are high in refined starches, added sugars, and saturated and trans fats and low in nutrient density. These strategies frequently overlap—for example, increasing the amount of fruit and vegetable ingredients in a menu item may also help to reduce overall fat content.

This chapter first describes three key issues relating to products, menu items, and meals: menu design and cooking techniques; portion size, plate composition, and menu pairing; and beverages. The chapter then sets forth four recommendations, along with specific operational tips for implementing the recommendations.

The recommendations and operational tips were developed with the following assumptions in mind.

- The target audience for this chapter is the foodservice industry, including producers and manufacturers, distributors, and foodservice operators. Because significant differences exist among these various sectors of the industry, the operational tips may not apply to all sectors. In addition, the operational tips provide examples for how to implement the recommendations and should not be considered all-inclusive.
- The scope of opportunity addressed in this chapter is limited to:
 - o products, defined as ingredients produced by manufacturers or growers and then generally sold to distributors for ultimate use by foodservice operators.
 - o menu items, defined as products or combinations of products in a recipe as they appear on a menu and that are, therefore, controlled by foodservice operators.

- o *meals*, defined as any combination of menu items that are sold to customers either individually or in predetermined combinations.
- Taste and freshness must be primary considerations, from the perspective of the foodservice industry, when seeking to fuel increased consumer demand for menu items and meals that will help with weight management. Market research studies have consistently shown that taste and freshness drive consumer demand for more healthful menu items and meals, rather than claims of "low calorie," "low fat," or other attributes. Hand recommendations and strategies in this chapter are based on the use of fresh fruits and vegetables, which understandably can create some constraints with regard to availability, preparation, and costs. For some foodservice outlets, therefore, it may be more feasible to use frozen or canned products, especially, for example, in cooked, multi-ingredient menu items, sauces, and other preparations in which the difference in flavor and texture will not be discernible.
- Education of those in the foodservice industry is a key component to the successful implementation of many of the recommendations.

Forum participants faced the following challenges and issues in the development of this chapter.

- The tone of the chapter is intended to be user-friendly in order to be embraced and accepted by the target audience, the foodservice industry.
- Although reducing calories is the main focus of this report, some, but not all, Forum participants felt strongly that it would not be responsible to put forward calorie-reduction recommendations that do not take nutrient density into consideration. Therefore, in addition to the focus on reducing calories, the recommendations and implementation strategies herein may refer to "healthful" or "healthier" choices for consumers, which is meant to signify foods that are nutrient-dense as well. In addition, as discussed in Chapter 2 and as recommended by the 2005 *Dietary Guidelines for Americans*, ¹⁴² the inclusion of whole grains in menu items and meals is encouraged; however, this topic is not addressed in any detail in this chapter.
- Consumer demand for the products, menu items, and meals suggested must exist already.
 Alternatively, a strategy for reaching out to the public could be developed, so that changes by industry will be accepted. Consumer demand ultimately drives the marketplace at every level within the foodservice industry, from the manufacturer/grower to the distributor to the operator. As discussed in Chapter 2, commercial and social marketing can help to shape demand.
- Some Forum participants noted the need for healthier children's menus in both quick-service and casual dining restaurants. Improved children's menus would include nutrient-dense,

¹⁴¹ B. Wansink, *Marketing Nutrition: Soy, Functional Foods, Biotechnology, and Obesity* (Champaign, IL: University of Illinois Press, 2005).

¹⁴² U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA), *Dietary Guidelines for Americans 2005* (6th ed.) (Washington, DC: HHS and USDA, 2005). See: www.health.gov/dietaryguidelines/dga2005/document/html/executivesummary.htm.

lower-calorie food choices, such as items containing fruits and vegetables and no- and low-fat dairy products. The issue of age-appropriate portion sizes also should be addressed in children's menus. In general, the healthier food choices made available to adults should be reflected in children's menus as well.

• Cost and price issues are of major concern. Studies reveal that diets low in calorie density are consistent with eating patterns described as healthy using other nutrient-based criteria. 143 Given the current structure of food prices, however, lowering dietary calorie density by replacing fats and sweets with vegetables and fruits can be associated with higher diet costs. 144 Sugar in any form, for example, is a very inexpensive food ingredient, while waterrich foods such as fresh produce, meats, and dairy products can be costly. 145 Such foods cost more to produce, transport, and store and have a shorter shelf life (leading to more spoilage) than dry grains, added sugars, and added fats. 146 As a result, many of the recommendations and operational tips included in this chapter will involve additional cost to the foodservice industry, in terms of both the cost of the products and the cost of operations. It is not clear that industry will be able to pass on all of these additional costs to all consumer segments—especially those at greatest risk for obesity and diabetes—thus making implementation of these recommendations challenging.

Overview of the Issues

The recommendations at the end of this chapter were framed around three central issues: menu design and cooking techniques; portion size, plate composition, and menu pairing; and beverages. Each of these issues presents opportunities for making changes in the away-from-home foods market.

Menu Design and Cooking Techniques

Traditionally, many households ate away from home for reasons of celebration, and they viewed the occasions as special opportunities for indulgence. As a result, foodservice industry systems—including cooking techniques, menu choices, equipment, and operational set-ups—were designed with that focus in mind. Also, when meals were consumed away from home relatively infrequently, their impact on caloric intake was less significant.

¹⁴³ S. Klein, et al., "Weight Management through Lifestyle Modification for the Prevention and Management of Type 2 Diabetes: Rationale and Strategies," a statement of the American Diabetes Association, the North American Association for the Study of Obesity, and the American Society for Clinical Nutrition, *American Journal of Clinical Nutrition* 80 (2004): 257-263; and J.H. Ledikwe, et al., "Food Patterns and Diet Quality of U.S. Adults with a Low-Energy-Dense Diet," *Journal of the American Dietetic Association*, in press.

¹⁴⁴ N. Darmon, A. Briend, and A. Drewnowski, "Energy-Dense Diets Are Associated with Lower Diet Costs: A Community Study of French Adults," *Public Health Nutrition* 7 (2004): 21-27.

¹⁴⁵ A. Drewnowski and S.E. Specter, "Poverty and Obesity: The Role of Energy Density and Energy Costs," *American Journal of Clinical Nutrition* 79 (2004): 6-16.

¹⁴⁶ B. Rolls, A. Drewnowski, and J. Ledikwe, "Changing the Energy Density of the Diet as a Strategy for Weight Management," *Journal of the American Dietetic Association* 105 (2005): S98-S103.

Now, however, the trend toward eating away-from-home foods is steadily increasing; the average consumer now eats 4.2 meals (or approximately 20% of all meals, based on 21 meals per week) outside the home per week, up from 3.9 per week in 1985. (The change is attributable to an increase in take-away foods; Americans are actually eating at restaurants less frequently—93 meals in 1985 versus 80 meals in 2005.) (This shift in consumers' lifestyles creates an opportunity for industry to modify its practices. This is not to say that the occasional indulgent meal should be eliminated from menus; however, to combat obesity, menu designs and routine cooking methods need to shift toward approaches that yield a greater percentage of healthier, lower-calorie, and less-calorie-dense menu choices.

By providing customers with new and/or reformulated menu items and meals of lower calorie density, restaurant and foodservice operators will help customers manage their energy balance. Studies show, for example, that consumers may not notice a 25% decrease in calorie density for many foods, and the change may have little effect on palatability. The addition of water-rich foods along with even modest decreases in fat content could reduce the calorie density of many popular foods, such as burgers, pizza, and sandwiches. With such reductions in calorie density, consumers are likely to ingest the same amount of food, but fewer calories, while feeling just as full and satisfied. (It is important to note, however, that the studies on which these statements are based were done in a laboratory setting; therefore it is difficult to discern what consumer acceptance would be in a more natural setting.) Two of the methods by which foodservice operators can reduce the calorie density of new or reformulated menu items and meals are as follows.

- Substituting less-calorie-dense versions of ingredients and products for their more-calorie-dense counterparts (e.g., substituting leaner meat or lower-fat cheese for the full-fat versions).
- Increasing the volume of fruits and vegetables in, and lowering the calorie density of, both individual items (e.g., by adding grated vegetables to meat dishes) and meals (e.g., by increasing the proportion of fruits and vegetables on the plate).

The ability to provide such menu items and meals, of course, is sometimes limited by operational realities. Foodservice operators can identify numerous obstacles that inhibit synergy among producers/manufacturers, distributors, and operators, and that ultimately restrict operators' ability to easily purchase and use the products needed to produce new or reformulated menu items and meals.

¹⁴⁷ R. Ebbin, "Americans' Dining Out Habits," *Restaurants USA*, November 2000. See www.restaurant.org/rusa/magArticle.cfm?ArticleID=138.

Harry Balzer, The NPD Group, *Eating Patterns in America*, presentation given February 1, 2006.

¹⁴⁹ B. Rolls, L. Roe, and J. Meengs, "Reductions in Portion Size and Energy Density of Foods Are Additive and Lead to Sustained Decreases in Energy Intake," *American Journal of Clinical Nutrition* 83 (2006): 11-7. ¹⁵⁰ Ibid. Also, B. Rolls, A. Drewnowski, and J. Ledikwe, "Changing the Energy Density of the Diet," 2005.

Portion Size, Plate Composition, and Menu Pairing

As discussed in the introduction to this report, obesity rates in the United States have increased dramatically over the past 30 years. During that same period, steady and significant increases have been documented in the portion sizes of foods consumed away from home, the number of away-from-home meals Americans are consuming, and Americans' overall calorie intake. Other factors may also have affected obesity rates during this time, including reduced physical activity, the trend for most households to be engaged in the workforce for pay and not have a full-time homemaker, an increase in the number of hours worked, and an increase in the number of single-person households. 152

Larger portions are common for many foods with a high calorie density, and while a causative link between large portions of calorie-dense foods and obesity remains unproven, the available data support such a link. Indeed, it has been shown that energy intake increases with bigger portions of a variety of types of foods, including those served in distinct units, such as sandwiches and potato chips, and those not served in distinct units, such as macaroni. The size of portions served in restaurants also affects calorie intake; one study found, for example, that when the size of a popular pasta dish was increased by 50%, customers ate 43% more of that dish. Survey data from the American Institute for Cancer Research indicate that many people let the foodservice provider determine an appropriate portion and eat accordingly, so that the bigger the portion, the more they consume.

As discussed in Chapter 2, a possible strategy for moderating the effects of portion size on calorie intake is to combine small decreases in portion size with moderate reductions in calorie density. In a recent study, when both the calorie density and portion size were reduced by 25% over two days, study participants showed a decrease in calorie intake of 812 calories per day. 158

Large portions are not associated with increased calorie intake in those cases where the food in question is low in calorie density. Studies show that consumption at the start of a meal of a low-

The Keystone Forum on Away-From-Home Foods—Final Report

¹⁵¹ L.R. Young and M. Nestle, "The Contribution of Expanding Portion Sizes to the U.S. Obesity Epidemic," *American Journal of Public Health* 92, no. 2 (2002): 246-249; L.J. Harnack, R.W. Jeffery, and K.N. Boutelle, "Temporal Trends in Energy Intake in the United States: An Ecologic Perspective," *American Journal of Clinical Nutrition* 71 (2000): 1478-1484; and J.J. Ledikwe, J. Ello-Martin, and B. Rolls, "Portion Size and the Obesity Epidemic," *Journal of Nutrition* 135 (2005): 905-909.

¹⁵² H. Stewart, et al., *The Demand for Food Away from Home: Full-Service or Fast Food?* Agricultural Economic Report #829 (Washington, DC: USDA, 2004).

¹⁵³ B. Rolls, et al., "Increasing the Portion Size of a Sandwich Increases Energy Intake," *Journal of the American Dietetic Association* 104 (2004): 367-372.

¹⁵⁴ B. Rolls, et al., "Increasing the Portion Size of a Packaged Snack Increases Energy Intake in Men and Women," *Appetite* 42 (2004): 63-69.

¹⁵⁵B. Rolls, E. Morris, and L. Roe, "Portion Size of Food Affects Energy Intake in Normal-Weight and Overweight Men and Women," *American Journal of Clinical Nutrition* 76 (2002): 1207-1213.

¹⁵⁶ N. Diliberti, et al., "Increased Portion Size Leads to Increased Energy Intake in a Restaurant Meal," *Obesity Research* 12 (2004): 562-568.

¹⁵⁷ B. Rolls, "The Supersizing of America: Portion Size and the Obesity Epidemic," *Nutrition Today* 38 (2003): 42-53; and American Institute for Cancer Research, *Awareness and Action: AICR Surveys on Portion Size, Nutrition, and Cancer Risk* (Washington, DC: AICR, 2003). See www.aicr.org/site/DocServer/ awarenessandaction_03conf.pdf?docID=106.

¹⁵⁸ B. Rolls, L. Roe, and J. Meengs, "Reductions in Portion Size and Energy Density," 2006.

calorie-dense food such as soup¹⁵⁹ or salad¹⁶⁰ actually decreases overall energy intake. This approach of eating low-calorie-dense food at the start of a meal may be an effective strategy for weight management, although it should be noted that it could also raise costs for consumers.

Beverages

Major consumer behavior changes have occurred in the past several years coincident with the obesity epidemic. One such change is an increase in the consumption of sugar-sweetened beverages, which is linked to higher calorie intake and a higher risk for obesity in some but not all studies. A recent study showed that the consumption of caloric beverages (e.g., sugar-sweetened soft drinks, 100% juices, and 1% milk) in contrast to non-caloric beverages (e.g., water or diet soft drinks) with a meal, added calories to the meal without impacting the subject's sense of fullness. Similar results were obtained when caloric beverages were consumed two hours before the meal. It would appear that consuming caloric beverages as opposed to water or other non-caloric beverages is likely to contribute to an excess consumption of calories.

Advice to limit sweetened caloric beverage consumption is consistent with the Dietary Guidelines, which advise consumers to "choose and prepare foods and beverages with little added sugars or caloric sweeteners." ¹⁶⁴ That said, Forum participants recognize that the development of obesity involves several dietary factors, ¹⁶⁵ and one of those factors is excess caloric intake. A decrease in caloric beverage consumption is just one of many necessary strategies in the effort to reduce obesity.

Soft drinks, which include soda, iced tea, sugary fruit drinks, and other sweetened beverages, are the largest single source of calories in the American diet. As soft drink consumption has increased, so have typical portions available for consumption. In the 1950s, for example, the standard serving size for soft drinks was $6\frac{1}{2}$ ounces. We now have a multitude of choices, including 12-ounce cans and increasingly popular 20-ounce bottles. In addition, fountain sodas of 32 and even 64 ounces are available in many venues. The larger the container, the more soda consumers are likely to drink, particularly when buying single-serving containers. The

The Keystone Forum on Away-From-Home Foods—Final Report

¹⁵⁹ B. Rolls, E.A. Bell, and M.L. Thorwart, "Water Incorporated into a Food but Not Served with a Food Decreases Energy Intake in Lean Women," *American Journal of Clinical Nutrition*, 70 (1999): 448-455.

¹⁶⁰ B. Rolls, L. Roe, J. Meengs, "Salad and Satiety: Energy Density and Portion Size of a First-Course Salad Affect Energy Intake at Lunch," *Journal of the American Dietetic Association* 104 (2004): 1570-1576.

¹⁶¹ R.A. Forshee and M.L. Storey, "Total Beverage Consumption and Beverage Choices among Children and Adolescents," *International Journal of Food Science and Nutrition* 54, no. 4 (2003): 297-307.

¹⁶² D. DellaValle, L. Roe, and B. Rolls, "Does the Consumption of Caloric and Non-Caloric Beverages with a Meal Affect Energy Intake?" *Appetite* 44 (2005): 187-193.

¹⁶³ E. Almiron-Roig and A. Drewnowski, "Hunger, Thirst, and Energy Intakes following Consumption of Caloric Beverages," *Physiology and Behavior* 79, no. 4-5 (2003): 767-73.

¹⁶⁴ HHS and USDA, Dietary Guidelines for Americans, 2005.

¹⁶⁵ American Beverage Association, "Obesity," www.ameribev.org/health/obesity.asp, accessed January 25, 2005. ¹⁶⁶ R.P. Troiano, et al., "Energy and Fat Intakes of Children and Adolescents in the United States: Data from the National Health and Nutrition Examination Surveys," *American Journal of Clinical Nutrition* 72 (supp.) (2000):

¹⁶⁷ B. Wansink and K. van Ittersum, "Bottoms Up! The Influence of Elongation and Pouring on Consumption Volume," *Journal of Consumer Research* 30, no. 3 (2003): 455-463.

introduction of self-serve beverage fountains and free refills may also be having an impact. (It is important to realize, however, that these latter developments are intentional positioning strategies for some restaurants and are an important part of their value proposition to consumers. ¹⁶⁸) Pricing practices also encourage people to drink large servings, as larger portions typically cost less per ounce. ¹⁶⁹

It is also worth mentioning that some specialty beverages, including flavored lattes and milkshakes, often deliver more sugar than do soft drinks. Their calorie content can be unexpectedly high, reaching up to 800 calories per 20-ounce portion. And as with soft drinks, a multitude of size choices are now available, with 16-ounce and 20-ounce lattes and cappuccinos more the norm than the exception. Thus the fat and sugar content of traditionally calorie-free coffee bears watching, as does its potential impact on the development of obesity. Also, as noted in the 2005 Dietary Guidelines, alcoholic beverages supply calories but few essential nutrients, and the caloric content of these beverages can vary widely depending on the volume of the drink, the types of mixers used, and other ingredients used. The Guidelines address issues related to moderate and excess alcohol intake, which were not a subject of discussion by the Forum nor a focus of its proposed recommendations. ¹⁷⁰

The Forum's Recommendations and "Operational Tips"

Forum participants in this section offer four recommendations and numerous operational tips for the consideration of the foodservice industry.

Recommendation 3.1

Promote the wider inclusion in foodservice of less-calorie-dense menu items and calorie-sparing cooking techniques that are widely accepted by consumers and that take into account constraints on operators.

Operational Tips for Recommendation 3.1

- 1) Culinary educational facilities should provide chefs and foodservice operators with the necessary education, resources, and skills to produce menu choices that will help customers achieve and maintain a healthy weight. Specifically, it is suggested that they do the following.
 - Provide instructional programs to help chefs and restaurateurs develop a solid understanding of (1) the science behind providing food choices that support healthy weight, (2) calorie density, and (3) the principles behind low-calorie-dense food selection and preparation.

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¹⁶⁸ B. Wansink and M. Huckabee "De-Marketing Obesity," *California Management Review* 47, no. 4 (2005): 6-18. ¹⁶⁹ National Alliance for Nutrition and Activity (NANA), *From Wallet to Waistline: The Hidden Costs of Super*

Sizing (Washington, DC: NANA, 2002).

¹⁷⁰ HHS and USDA, Dietary Guidelines for Americans, 2005.

- Provide educational programs that illustrate how to develop less-calorie-dense menu items. For example:
 - o Encourage the use of fruit- and vegetable-based sauces in place of high-calorie-dense sauces.
 - o Emphasize the moderate use of healthy (i.e., unsaturated) fats, which should be added to a product where they will have the greatest impact on flavor.
 - o Encourage the use of fruit-based desserts in place of butter- and cream-based, high-sugar preparations.
- Provide educational programs to help chefs and restaurateurs overcome the perception that healthy menu items lack creativity and flavor. The following are examples of strategies that optimize flavor, taste, and customer appeal.
 - o Highlight peak-of-flavor seasonal produce.
 - Explore a variety of world cuisines for inspiration regarding healthy cooking and menu design—specifically, cuisines that are largely plant-based and include innovative ways to enhance flavor and present produce-centered preparations.
 - Highlight the use of high-flavor, low-calorie-dense ingredients such as fresh herbs and spices.
- Encourage chefs and restaurateurs to offer more lower-calorie choices on children's menus. Encourage them to:
 - o Consider children's menus to be an extension of the regular menu.
 - Offer more fruits and vegetables on the children's menu.
 - o Offer appropriate portion sizes of children's meals.
 - o Make lower-calorie beverages the default option with children's meals.
 - O Direct this strategy at culinary leaders in the multi-unit sector, who are in the best position to innovate in this part of their menu.
- Include food distributors in discussions about how to implement this recommendation.
- 2) To help promote the educational priorities described above, appropriate government agencies should:
 - in conjunction with industry, support initial educational and leadership efforts as follows.
 - Convene roundtable discussions at various trade and professional conferences and culinary schools, to engage foodservice operators and chefs in a dialogue about creative ways to offer flavorful and healthier menu items.
 - Convene a "speakers series" in which renowned experts present the findings and recommendations from this report at various trade and professional conferences.
 - Provide grants to help culinary schools develop curricula or other resource materials that reflect the current consensus within the scientific community about cooking methods and approaches that help consumers achieve and maintain a healthy weight.
 - Work to raise awareness within the industry about the need for foodservice operators to be educated about healthy cooking techniques.

- 3) The synergy between producers/manufacturers, distributors, and operators should be enhanced, in order to facilitate the purchase and use of the products that are needed to produce new or reformulated menu items and meals, to help consumers manage their energy intake.
 - Industry leaders, distributors, and other appropriate individuals should initiate conversations with growers regarding opportunities for increased production of the most commonly used fruits and vegetables.
 - Industry leaders and appropriate government agencies should encourage manufacturers to develop and promote alternative produce packaging—such as cryovac, sous vide, aseptic, and ready-to-cook packaging—which requires less refrigerator/freezer storage and less preparation time and skill, and improves the sensory quality of the produce (compared to standard freezing and canning methods).
 - Industry leaders and appropriate government agencies should encourage manufacturers to offer foodservice-size packaging for products such as evaporated fat-free milk, lower-fat cheeses, and precut vegetables, all of which can be used to make less-calorie-dense menu items
 - Large purchasers and purchasing consortiums, which have the power to influence distribution methods, should:
 - o provide incentives to distributors to offer split cases, small quantities (by the piece), and more frequent deliveries for operators with small volume and/or limited storage.
 - o provide incentives to distributors to offer partially prepared produce (cleaned, peeled, cut), as well as low-fat and nonfat dairy products.
 - promote a reasonable, but not excessive, price premium for those services requiring substantial additional labor, assuming that consumer demand will permit the premium.
 - In appropriate foodservice settings, operators should train employees to clean, peel, and cut fresh produce.
 - In appropriate foodservice settings, operators should train employees to ask produce vendors and distributors for advice on the "best buys" in terms of flavor, seasonality, and price.
 - Operators should purchase fruits and vegetables in season when possible.
 - Operators, including those who operate quick-service and fast-casual restaurants, are encouraged to use fruit- and vegetable-based "limited time offers," such as pumpkin specials in the fall and cranberry specials in the winter.
 - Operators should patronize vendors and distributors that will provide them with split
 cases, more frequent delivery, pre-prepared fruits and vegetables, lean meats, and low-fat
 and nonfat dairy products.

- Operators should increase their usage of fruits, vegetables, and other products, such as low-fat and nonfat milk and cheese or lean meats, in order to reduce the calorie density of their menu items and meals by a mutually agreed upon percentage.
- The U.S. Department of Agriculture or other appropriate entities should be urged to compare the forecasted demand for fruits and vegetables with actual production levels, and then promote opportunities where an excess supply exists.

Funding Approaches

Funding to implement this recommendation could come from a variety of sources, including governments, foundations, corporations, and associations. Ideally, appropriate government agencies would first fund leadership programs (i.e., "train the trainer" programs) to stimulate initial activity and create awareness of shared long-term industry goals. Costs are difficult to predict, but the focus should be on funding the development of educational resource materials for the foodservice industry, as well as pilot programs to demonstrate success.

Recommendation 3.2

Foodservice providers should develop and promote portion-size, plate composition, and menupairing options that help consumers in their efforts to manage their energy intake.

Operational Tips for Recommendation 3.2

The following implementation strategies are geared toward chefs, menu developers, servers, and customers.

- 1) Reduce total calories in mixed dishes by combining moderate reductions in calorie density with changes in portion size.
 - Bundle menu items or retool the plate to increase or add portions of fruit and vegetables. Some suggest re-portioning the plate so that four key elements—the main dish, fruits, vegetables, and whole grains—each make up one-quarter of the plate.
 - Use small amounts of fish, lean meat, poultry, nuts, legumes, and/or eggs to create "center-of-the-plate" entrees that are largely plant-based (though not necessarily vegetarian).
- 2) Retool menu items to provide less-calorie-dense choices.
 - Offer lower-calorie condiments, such as mustard, salsa, and full-flavor sauces.
 - Decrease the portion size of calorie-dense spreads and protein sandwich fillings (e.g., tuna salads, chicken salads, etc.).
 - Offer half portions.
 - Offer sandwich alternatives, such as lettuce wraps.

- Where it would not compromise taste, use reduced-calorie or reduced-fat ingredients, such as mayonnaise, cheese, milk, and leaner meats, or use smaller amounts of the calorie-dense ingredients.
- Offer salads with the "extras" on the side (e.g., croutons, bacon bits, cheese, salad dressing).
- Prepare vegetables, fish, and other menu items using more-healthful cooking techniques (e.g., steaming, baking, and grilling), and top them with nutrient-dense, low-calorie sauces and flavor enhancers rather than traditional, calorie-dense sauces.
- Increase opportunities for customers to customize their meals with less-calorie-dense options.
- 3) For sandwiches, offer more fruit and/or vegetable options than just lettuce and tomato. For example, offer roasted red peppers, roasted eggplant, cucumbers, etc.
- 4) Provide more options and promote (i.e., "suggestive sell") meal bundles with fruits and vegetables (including salads), while maintaining traditional side options as well.
 - Focus on providing more age-appropriate options for children's meals, including more fruits and vegetables. Also, include low-fat and/or fat-free milk in bundled meals for children
- 5) Develop and promote appropriately sized "sampler" plates of bite-sized appetizers and desserts (including a combination of indulgent and healthier options) to be shared, with the goal of thereby reducing the total calorie intake of one's overall meal.
- 6) Offer several portion sizes of each menu item.
- 7) Feature ethnic cuisines that inherently encourage small portions, such as tapas, mezze, and dim sum.
- 8) Adopt approaches to support portion-size reduction and/or curtail emphasis on "bigger means better" messages. For example:
 - Industry could refrain from using value marketing to promote larger portion sizes. Value messages based on "a large amount of food for a fixed price" could be replaced with value messages based on a "small portion of food for a *lower* price." The large size could still be made available if desired.
 - Government, industry, and health groups should conduct joint social marketing campaigns to help people understand appropriate portion sizes for their calorie needs.

Cost Considerations

Smaller portion sizes do not necessarily equate to lower costs, especially if menu items are made more healthful through the addition of fruits and vegetables. Increased costs to execute the above strategies might include food, labor, research and development, and marketing costs, which would be incurred by foodservice operators and most likely passed on to consumers. Some consumers may be willing and able to pay a higher price for these options, but some may be unable or unwilling. Some of these costs (especially for research and development) could be

minimized if they were shared among government agencies, health groups, and industry. As discussed in Chapter 2, marketing and education initiatives are needed to promote the value of these changes to consumers.

Recommendation 3.3

Foodservice providers should develop, make available, and promote beverage options that help consumers to reduce calorie intake.

Operational Tips for Recommendation 3.3

Industry leaders should do the following.

- 1) Increase the range of low-calorie or zero-calorie beverage choices available to consumers and provide smaller portion sizes (e.g., 10-fluid-ounce sizes, 100-calorie servings, etc.)
 - Where fountain drinks are self-served, provide a wider variety of selections, such as unsweetened flavored waters or seltzer, light or no-calorie lemonade or fruit drinks, unsweetened and/or non-caloric sweetened iced teas, diet colas, and diet non-cola sodas.
 - When serving bottled beverages, a similar range of options should be included, in addition to water
- 2) Increase the selection of low-fat or nonfat milk beverages. Although the calories in nonfat milk are equivalent to the calories in sodas and juices, milk provides important nutrients that are lacking in many Americans' diets. ¹⁷¹
 - Fat-free and 1% milk should be readily available, especially with children's meals.
 - Organizations and government agencies should collaborate on campaigns to encourage low-fat milk consumption and on strategies to close the gap between current consumption levels and the intake levels recommended in the 2005 Dietary Guidelines. A number of communities have conducted "1% Or Less" campaigns, which have resulted in significant increases in low-fat milk sales and consumption.
- 3) In specialty venues such as coffee shops, offer lower-calorie selections and smaller portion sizes of specialty and frozen drinks, in addition to the standard versions.
 - Where this is already occurring, it would be helpful to compile data on product performance.
- 4) Expand the range of beverage options available to consumers to include a wider array of cup and bottle sizes.
- 5) Consider pricing approaches that make smaller sizes and lower-calorie options more appealing.

 $^{^{171}}$ C.S. Berkey, et al., "Sugar-Added Beverages and Adolescent Weight Change," *Obesity Research* 12, no. 5 (2004): 778-788.

6) For bundled meals, offer lower-calorie beverage options, such as water, and encourage reasonable portion sizes.

Recommendation 3.4

Industry and academia should conduct—collaboratively, if possible—research on the topics and questions listed below. In addition, a specific scientific survey should be conducted about the experiences of operators and restaurateurs in developing menu items that could aid in weight management.

Many of the recommendations above that are geared toward industry are not based on empirical research. As a result, researchers in industry and/or academia should make an effort to validate these recommendations. In so doing, a collaborative effort between these entities would be beneficial to the field. One goal of such a collaborative effort should be to assess the effectiveness of each proposed strategy in restaurant and institutional settings. Strategic partnerships between the scientists conducting the research and the restaurateurs providing the real-world laboratory could help to close the knowledge gaps that currently exist. Some of these knowledge gaps are identified below, followed by information about a preliminary survey that was developed to gather more information about the experiences of operators and restaurateurs in developing menu items that could aid weight management.

Basic Research Needs

The following suggestions focus on research as it relates to the foodservice industry (as opposed to the consumer). They address basic research needs as well as suggestions for the development of specific, scientifically sound strategies that will lead to a better informed public, industry, and academic community. The proposed research will hopefully lead to a fuller body of knowledge that will support and encourage additional changes in products, menus, and meal items to address the problem of overweight and obesity.

Basic research needs and questions are categorized into four topics below: calorie density and portion size; increasing fruits and vegetables; product formulation; and packaging and marketing.

- 1) Calorie Density and Portion Size
 - What is the relationship between calorie intake, portion size, and satiety in the long term?
 - Can portion sizes be made to more accurately reflect caloric needs, while continuing to deliver acceptable value and an equal level of acceptance by consumers?
 - Is it feasible to reformulate popular menu items to decrease calorie density while maintaining price or preserving, or even increasing, market share?
 - How can reductions in portion size and calorie density be combined to help consumers reduce calorie intake?
 - Can shifts in menu offerings be made to reflect the appropriate balance of foods (i.e., as recommended by the Dietary Guidelines¹⁷²)?

¹⁷² HHS and USDA, Dietary Guidelines for Americans, 2005.

2) Increasing Fruits and Vegetables

- Do individuals who consume the amount of produce recommended in the Dietary Guidelines tend to have a healthier weight?
- What costs are associated with re-portioning the plate to include a greater volume of fruits and vegetables in a meal, and under what conditions will those costs be accepted by the consumer?
- What fruit and vegetable options are "desirable" in the away-from-home foods market—both in terms of those that consumers will select and those that help to reduce calorie intake? The answers to this question might differ for various sectors (e.g., quick service, fast casual, fine dining).
- Based on a hypothetical target increase for fruit and vegetable consumption in restaurants, develop a forecasting tool to help predict potential demand for the ten most commonly used fruits and vegetables. Utilize this information to help industry become better equipped to reach the target.

The following five recommendations were taken from the Produce for Better Health National Action Plan. Forum participants considered them to be relevant to the purposes of this report and therefore have reiterated them here.

- Fund agricultural research initiatives that address convenience, taste, versatility, and longer-term product quality issues (from farm to table) regarding fruits and vegetables.
- Support increased research into the role of fruits and vegetables in weight management (including preparation techniques, when and how fruits and vegetables are consumed, and satiety functions).
- Support increased emphasis on fruit and vegetable research that focuses on increasing consumer consumption.
- Develop measurement and impact tools to evaluate the effectiveness of various fruit and vegetable consumer marketing initiatives.
- Support studies of the relative roles various factors play in fruit and vegetable consumption among children and adults—availability, price, education, type of produce, type of other foods offered, age, parental involvement, and media messages.

3) Product Formulation

- How would operations and product pricing be affected by the recommended product formulation changes in menu items, and how would this affect the cost to the consumer?
- What attributes of "healthy" products (e.g., lower sodium or fat, flavor, characteristics unrelated to their healthfulness, price, freshness, general quality, etc.) cause them to fail? Can any generalizations be made, or does each product need to be considered on a case-by-case basis?
- If presented with a wider variety of healthy choices, what decisions will consumers make? And do those decisions have an impact on weight management? (For example, will consumers choose lower-fat cheese on sandwiches, no cheese on salads, low-calorie dressings, low-calorie beverage options, etc.?)

¹⁷³ Produce for Better Health Foundation, *National Action Plan to Promote Health through Increased Fruit and Vegetable Consumption* (Wilmington, DE: Produce for Better Health Foundation, 2005).

- What changes in children's menus will impact pediatric overweight and obesity? These changes might include: smaller portion sizes and offering more fruits, vegetables, low-fat dairy products, leaner meats, and lower-calorie beverages.
- Can the history of successes and failures in terms of recent initiatives (over the past two years) by foodservice establishments provide valuable insight into new product offerings or reformulations?

4) Packaging and Marketing

- What information do consumers either lack or need in order to make informed decisions at the point of consumption?
- Would it be useful to encourage restaurants to promote the use of "to go" containers with meals so that consumers eat less in one sitting?
- Are commercial sizes of lower-calorie products (e.g., low-fat cheese, fat-free evaporated milk, etc.) available in sufficient quantity and variety?
- What information, if any, regarding the nutritional composition of menu items prompts consumers to take action and choose items to manage weight?

Scientific Survey

Keystone Forum participants conducted an informal survey to gather information from chefs and restaurant owners about their experiences helping customers to manage their weight and health, particularly via product reformulation and innovation. The purpose of this unscientific, preliminary survey was to better understand the current thinking in the food industry on these topics. The group hoped to identify some additional recommendations through this exercise. Based on the narrow range of results, however, in which 92 of the 111 responses were from the on-site/contract-feeding sector, participants were not comfortable putting forth concrete recommendations based on these responses.

Forum participants did, however, see promise in these preliminary results and therefore recommend that a scientific survey be conducted after the conclusion of the Forum. Collecting such information from chefs, restaurant owners, managers, and others across the spectrum of industry sectors, as well as researchers and public policy officials, will further public understanding of what changes the restaurant industry might be encouraged to undertake in the future. This type of information could provide guidance to the industry on how to develop menu items that will help consumers manage their weight.

Appendix G contains information about the results of the informal study.

Chapter 4 Providing Consumers with Nutrition Information

When making decisions about away-from-home foods, consumers often may not have access to nutrition information to inform their selections and eating behaviors pursuant to appropriate energy intake. This chapter includes Keystone Forum participants' findings and recommendations regarding how to increase consumer access to such information. The chapter begins with an introduction to the issue of providing nutrition information for away-from-home foods. It then covers four key aspects of the topic: (1) potential objectives for providing such information; (2) special considerations relating to the away-from-home foods sector; (3) consumer use of such information; and (4) the federal government's role in providing such information. The chapter concludes with the Forum's recommendations regarding nutrition information and away-from-home foods.

Introduction to the Issue

Whereas a growing number of foodservice venues voluntarily provide some information about the caloric and nutritional content of their menu items, many do not. Available information may be provided in different formats (e.g., websites, brochures, kiosks), focus on different nutrients (e.g., calories, carbohydrates, fat), and take a variety of forms (e.g., numerical values, symbols, written characterizations of health attributes). Without nutrition information, consumers typically are unable to assess the caloric content of foods. 174

Consumer interest in nutrition information may vary by type of foodservice venue, consumer demographic characteristics, and other factors. Recent polls suggest that, in general, consumer interest in nutrition information at foodservice establishments is increasing. Four national polls have found that at least 60% of respondents would like calories to be listed on menus or menu boards in chain restaurants. ¹⁷⁵ In another recent survey, conducted by ARAMARK, 83% of

¹⁷⁴ W.G. Johnson, et al., "Dietary Restraint and Eating Behavior in the Natural Environment," *Addictive Behaviors* 15 (1990): 285-290; J. Backstrand, et al., *Fat Chance* (Washington, DC: Center for Science in the Public Interest, 1997); and Scot Burton, et al., "To Eat or Not To Eat: Effects of Objective Nutrition Information on Consumer Perceptions of Fast Food Chain's Meal Healthiness, Future Health Concerns, and Meal Repurchase Intentions," *publication pending*.

¹⁷⁵ Lake, Snell, Perry & Associates, "Obesity as a Public Health Issue," a poll commissioned by the Harvard Forums on Health in 2003, with 1,002 respondents nationwide, www.phsi.harvard.edu/health_reform/poll_results.pdf, accessed March 18, 2006; Global Strategy Group, "Menu Board Question," a poll commissioned by the Center for Science in the Public Interest in 2003 with a nationally representative sample of 600 respondents, http://cspinet.org/new/pdf/census_menu_board_question.pdf, accessed March 18, 2006; Time/ABC News poll, conducted May 10-16, 2004, with 1,202 respondents nationwide; and Field Research Corporation, "A Survey of Californians about the Problem of Childhood Obesity," a poll commissioned by the California Endowment in November 2003 with 1,068 respondents in California, www.calendow.org/reference/publications/ disparities in health.stm, accessed March 18, 2006.

respondents said that restaurants should make nutrition information available for all menu items. ¹⁷⁶ The findings from these polls are summarized in Appendix H. (It should be noted that, in general, polling questions may elicit varying responses depending on how the questions are phrased and in what context.)

About half of the nearly 300 largest chain restaurants in the United States provide some kind of nutrition information to their customers in one format or another (such as on websites, posters, packaging, brochures, or kiosks). The National Restaurant Association has launched the Ask Us! program, a voluntary, nationwide, branded effort to help nutrition-conscious customers make informed menu choices. Participating restaurants receive free resources for use in the delivery of nutritional data to customers.

In addition, over the past five years, several government or government-sponsored reports have encouraged the widespread provision of nutrition information to consumers. A 2001 report on obesity from the U.S. Surgeon General called for the "increasing availability of nutrition information for foods eaten and prepared away from home." *Calories Count*, a 2004 report from the Food and Drug Administration's Working Group on Obesity, urged the restaurant industry to launch a "nationwide, voluntary, and point-of-sale nutrition information campaign for consumers," and encouraged consumers to "routinely...request nutrition information in restaurants." *A 2004 report on pediatric obesity by the National Academies' Institute of Medicine called for full-service and fast-food restaurants to "provide general nutrition information that will help consumers make informed decisions about food and meal selections and portion sizes." *179

Evidence regarding how and why consumers use nutrition information is limited. Outstanding questions include how consumers process and use such information, what measurable contribution the information can make to the goal of managing weight gain and obesity, where the point of decision-making is for away-from-home-foods consumers, and what effect information may have on consumer choice, eating behavior, and store revenue. Likewise lacking are data with regard to whether one format or another alters the rate of consumer usage of the information.

Lastly, owing to variance in preparation, sourcing, and other factors, some Forum participants are concerned that nutrition information in the away-from-home foods sector cannot always achieve the same level of accuracy and reliability that consumers expect from packaged food labels. Menu and recipe variability may make the regular provision of nutrition information particularly difficult for at least some foodservice establishments. Culinary education in the

¹⁷⁶ C. Malone and J. Bland-Campbell (ARAMARK), *New Insights on the Away-From-Home Eating Patterns and Nutritional Preferences of Americans*, presentation at the North American Association for the Study of Obesity Annual Scientific Meeting, October 17, 2005. See

www.aramark.com/CaseStudyWhitePaperDetail.aspx?PostingID=420&ChannelID=221.

¹⁷⁷ U.S. Department of Health and Human Services (HHS), *The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity* (Rockville, MD: HHS, 2001).

¹⁷⁸ U.S. Food and Drug Administration (FDA), *Calories Count: Report of the Working Group on Obesity* (Rockville, MD: FDA, 2004).

¹⁷⁹ Institute of Medicine, *Preventing Childhood Obesity: Health in the Balance* (Washington, DC: National Academies Press, 2004).

United States teaches chefs to cook by proportion, touch, and feel rather than by following standardized recipes. Indeed, restaurants and foodservice establishments that employ trained chefs typically do not follow recipes. There is concern that, by encouraging all foodservice establishments to provide nutrition information to consumers, those venues that do not use standardized recipes may unintentionally provide erroneous information to consumers.

Potential Rationales for Providing Nutrition Information for Away-from-Home Foods

Forum participants agreed generally on the value of providing nutrition information to consumers, as noted later in Recommendation 4.1, but they did not agree on the rationales for why that information should be provided. The range of views on this topic, outlined here, may help the reader to understand the complexity of the issue and the diverse and sometimes strong views that the topic generates among stakeholders.

Some Forum participants argued that nutrition information should be provided if and when consumers demand it. If consumers demand more nutrition information in restaurants and other away-from-home food outlets, businesses will provide it. Others noted that consumer demand is not static, but can be influenced by commercial marketing and, to a lesser extent, social marketing and government education. Some said that consumers have a right to know about the products they purchase generally, including the nutrient content of away-from-home foods specifically. Some participants, noting the experience of the Nutrition Labeling and Education Act (NLEA, which required certain nutrition information on packaged grocery items), reasoned that by providing nutrition information, away-from-home food providers will be encouraged, out of competition and the desire to promote "healthy" products, to reformulate their products to decrease components such as calories and fat without unduly affecting cost or taste. Thus, whether or not consumers make more healthful choices, they will consume reformulated products with fewer calories and fat.¹⁸⁰

Forum participants also discussed whether the goal of influencing consumer behavior to help consumers better manage weight gain and obesity was appropriate. Some believe, given that obesity and overweight are significant public health concerns, and their consequences can include both morbidity and mortality, that it is wholly appropriate to actively seek to influence consumers' behaviors. Others believe that consumers' choices must be respected and protected, and that, while providing information in the marketplace was generally appropriate, providing information with the intent of changing consumers' choices was fraught with value judgments about what, why, and how people should eat.

Some Forum participants also stated reasons why nutrition information should potentially not be provided. For example, they said that providing nutrition information (1) might not change consumers' behavior (at least not alone, as already noted in this report, since one specific action is not likely to single-handedly change consumer behavior), (2) might be costly, and (3) might

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¹⁸⁰ See E. Golan, et al., "The Economics of Food Labeling," *Journal of Consumer Policy* 24, no. 2 (2001): 117-184 (also published by the U.S. Department of Agriculture (USDA) Economic Research Service (ERS) as Agricultural Economic Report #793, December 2000).

introduce unanticipated changes in consumer demand (i.e., consumers might start avoiding highly profitable items or switch the source of their meals from one outlet to another).

Considerations for the Away-from-Home Sector

For the away-from-home foods industry, providing nutrition information—be it due to requirements, market demand, or for general public benefit—has a variety of implications. Away-from-home foods are exempt from nutrition labeling requirements under the NLEA if they bear no nutrition claims or other nutrition information. (Fresh vegetables and meats are also exempt, as the NLEA applies primarily to packaged foods.) In many foodservice venues, the same meal may be sourced from a variety of regional and varying suppliers, and fresh, raw ingredients may be used. Cooks and chefs may vary ingredients and recipes (and thus calorie contents), for reasons of taste, quality, and availability—from establishment to establishment and even day to day and month to month. Fine dining and other foodservice venues may not use recipes at all. Many types of venues also consider it a business imperative to allow for the customization of orders. Finally, the industry is notable for its vast variety of types of venues from independent lunch counters to multinational quick-service chains, from daily-use, on-site employee cafeterias to fine-dining establishments. For all these reasons, many stakeholders within and outside of the industry—believe that any approach to providing nutrition information must take into account variables that are unique to away-from-home foods generally and to specific venues.

Several factors should be considered regarding the provision of nutrition information and its impacts on business, including:

- the type and extent of information provided;
- how meaningful the information is to consumers;
- the time it takes to implement;
- the cost to implement (both direct costs as well as indirect costs such as reformulation, which might result if operators choose to change the nutritional profile of offerings);
- operational practicability and feasibility;
- the potential liability created by voluntarily providing information, or the potential reduction in liability for having widely accepted criteria for the provision of the information;
- impact on speed of service, especially for quick-service restaurants;
- impacts on revenue, market share, and consumer substitution within an establishment, across establishments, and even across sectors;
- the potential benefits and disadvantages of having a level playing field for the provision of nutrition information; and
- the potential value of standards in providing consistency across businesses and companies (and the questions of who should act, who should pay for it, what the parameters should be, and what margin of error is appropriate).

Consumer Use of Nutrition Information

Evidence regarding how and why consumers use nutrition information is limited. However, there is some evidence—gleaned through website hits, brochure disappearance, customer inquiries, consumer focus groups, polls, and in-store experiments—that many consumers generally value the information.

Some Forum participants believe that helpful lessons regarding consumers' use of nutrition information may be drawn from research into the consumer use of nutrition information printed on packaged foods. Three-quarters of adults report using food labels. While studies are limited, existing evidence finds that using food labels is associated with eating more-healthful diets. About half (48%) of people report that the nutrition information on food labels has caused them to change their minds about buying a food product—a 50% increase over the number in a survey conducted before the food labeling law was implemented. 183

The data collected since the NLEA was implemented in 1994 suggest that people tend to use food label information to compare "like" products rather than to make selections across product lines. For instance, someone may choose one yogurt over another after comparing labels, but they do not tend to choose between yogurt and a cookie by comparing those two labels. Some, but by no means all, Forum participants believe that if consumers use nutrition information similarly, this approach might prove effective in restaurants. Restaurants offer many fewer choices (often 50 to 200 menu items) than supermarkets (often 40,000 to 50,000 products), and all or many items are typically listed together in a single place—on the menu board or menu.

It is estimated that strengthening food labeling can yield significant health and economic benefits. The Food and Drug Administration (FDA) estimated in its rulemaking that requiring trans fat content to be listed on packaged-food labels would avoid more than 240 deaths per year at an initial cost of up to \$275 million, and produce benefits totaling between \$968 million and \$1.97 billion annually in today's dollars, depending on the calculation method. These dollar figures reflect the value of preventing both mortality and morbidity and include saved medical costs plus the dollar value of statistical lives saved and quality-adjusted life-years saved. The U.S. Department of Agriculture (USDA) estimated the economic benefits of extending nutrition labeling to fresh meat and poultry to be \$62 million to \$125 million per year, though they have

¹⁸¹ Centers for Disease Control and Prevention (CDC), National Center for Health Statistics (NCHS), *Healthy People 2000 Final Review* (Hyattsville, MD: CDC, NCHS, 2001).
 ¹⁸² S.Y. Kim, R.M. Nayga, and O. Capps, "The Effect of Food Label Use on Nutrient Intakes: An Endogenous

The Keystone Forum on Away-From-Home Foods—Final Report

Switching Regression Analysis," *Journal of Agricultural Resource Economics* 25 (2000): 215-231; M.W. Kreuter, et al., "Do Nutrition Label Readers Eat Healthier Diets? Behavioral Correlates of Adults' Use of Food Labels," *American Journal of Preventative Medicine* 13 (1997): 277-283; and M.L. Neuhouser, A.R. Kristal, and R.E. Patterson, "Use of Food Nutrition Labels Is Associated with Lower Fat Intake," *Journal of the American Dietetic Association* 99 (1999): 45-50, 53.

¹⁸³ A.S. Levy and B.M. Derby, *The Impact of the NLEA on Consumers: Recent Findings from FDA's Food Label and Nutrition Tracking System*, paper prepared for the FDA Office of the Commissioner, January 1996. ¹⁸⁴ FDA, "Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Final Rule," *Federal Register*, July 11, 2003.

not sought to mandate such labeling.¹⁸⁵ In a recently completed white paper, the authors estimate that the monetary benefit (including lower mortality risk, lower medical expenditures, reduced absenteeism, and increased productivity) for non-Hispanic white women of a decrease in body weight associated with the NLEA ranges from \$63 billion to \$166 billion over 20 years beginning from 1991, the year after the law was passed.¹⁸⁶

A key benefit of mandatory nutrition labeling on packaged foods has been the reformulation of existing products and the introduction of new, nutritionally improved products. ¹⁸⁷ Between 1991 (before the implementation of the NLEA) and 1995 (after implementation), the number of available fat-modified cheese products tripled, and the market share for fat-modified cookies increased from zero percent of the market to 15%. ¹⁸⁸ In a similar fashion, nutrition labeling on menus and menu boards may spur nutritional improvements in restaurant foods.

Some participants, however, are wary of extrapolating from the experience of packaged foods to the away-from-home context, in which accuracy is harder to achieve and consumers may be more likely to grant themselves license to indulge (due to a special occasion, for instance) and therefore may be less interested in nutrition information.

Also, some participants believe that the introduction of nutrition labeling on packaged foods may have had a bigger impact on food choice if it had been accompanied by a greater investment in helping people to understand and utilize the information. While Forum participants generally support the provision of nutrition information, many believe its effectiveness in assisting consumers with managing their energy intake is enhanced by supporting education that provides guidance in interpreting and making use of the information.

A review of the current literature on the consumer use of nutrition information regarding away-from-home foods is included in this report as Appendix I. Evidence regarding how and why consumers use nutrition information in away-from-home foods settings is limited. There may be important policy reasons (e.g., right to know, do no harm, act now in the face of uncertainty due to the magnitude of the problem) to take action on the basis of existing knowledge.

In the research to date, the literature suggests that:

- a majority of those surveyed in national polls want calorie and other nutrition information on restaurant menus;
- consumers, and nutrition experts for that matter, are not able to accurately estimate the caloric content of away-from-home foods:
- different population segments may react to and use nutrition information differently (i.e., women may use it more than men to make lower-calorie selections, consumers with health conditions like heart disease may react more favorably and use information such as specific

¹⁸⁵ S. Crutchfield, F. Cutchler, and J. Variyam, "The Economic Benefits of Nutrition Labeling: A Case for Fresh Meat and Poultry Products," *Journal of Consumer Policy* 24, no. 2 (2001): 185-207.

¹⁸⁶ J. Variyam and J. Cawley, *Nutrition Labels and Obesity*, National Bureau of Economic Research (NBER) Working Paper #11956 (Cambridge, MA: NBER, 2006).

¹⁸⁷ B.A. Silverglade, "Food Labeling: Rules You Can Live By," *Legal Times*, July 17, 1995: 21-24.

¹⁸⁸ Levy and Derby, "The Impact of the NLEA on Consumers," 1996.

- calorie counts or health-oriented symbols, and some consumers may not make lower-calorie selections even when clear, detailed nutrition information is provided); and
- consumers tend to make more significant changes to their choices when the caloric content of a product or meal is significantly higher than expected or perceived.

In addition, many in the industry have found in their experience that using "healthy symbols" can unintentionally reduce demand for products, and proprietary data may exist to support this experience. In the limited published literature, however, the research done to date has not shown a correlation between healthy symbols and decreased demand. Also, published research is not available on how and where nutrition information should be provided to best help people lower their calorie intake in away-from-home food establishments.

Differences in experimental methods, subject populations, labeling approaches, and other factors suggest that care should be taken when generalizing from these findings. A number of authors note that an examination of the effects of information provision in restaurant-type settings or other away-from-home contexts is difficult.

The Role of Government in Providing Nutrition Information

Away-from-home food providers are not bound by any federal regulatory requirements to provide nutrition information about menu items, unless they make specific health or nutrient content claims. When provided, it must be truthful and not misleading. Though federal and state governments provide a host of broad information and education on overweight and obesity and collect some data through the USDA's Economic Research Service, the FDA does not have regulatory authority to require nutrition information in restaurants.

The U.S. Congress and state legislatures do have the authority to require the provision of nutrition information, and a number of these elected bodies have considered nutrition labeling bills. Between 2003 and 2005, 14 states, ¹⁸⁹ the District of Columbia, the U.S. Senate, and the U.S. House of Representatives introduced legislation to require nutrition information disclosure at restaurants. Generally, the bills would require calories and/or other nutrition information to be listed on menus or menu boards, limit the requirement to chain restaurants (defined as restaurants with 10 or 20 or more outlets operating under the same trade name nationally), and limit the required information to calories, saturated plus trans fat, sodium, and carbohydrates. To date, none of the bills has been signed into law.

Government agencies might play any number of roles in increasing consumer access to nutrition information. They could continue to provide general information and gather consumer and producer data. The federal government could issue non-binding guidelines on how to develop accurate nutrition information for away-from-home foods within certain tolerances, in order to help industry as a whole develop common and best practices and to help assure consumers that the information they receive is accurate and consistent across outlets. The federal government could also issue binding regulations (if authorized to do so by Congress) outlining what kind of

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¹⁸⁹ Arkansas, California, Connecticut, Hawaii, Illinois, Maine, Massachusetts, New Hampshire, New Jersey, New York, Ohio, Pennsylvania, Texas, and Vermont.

information to provide and where and how to provide it, and allowing for prescribed tolerances for accuracy (as done under the NLEA and its associated regulations) for one or more segments of the away-from-home foods sector.

The following are some of the arguments made for and against an additional role for the federal government in ensuring that nutrition information is available for away-from-home foods. 190

- Right to Know (as noted earlier): Consumers have a right to know about the products that they purchase. Because providers of products tend to have access to more information, be more concentrated, and have more resources, they have greater power to provide or withhold information to achieve their goals and objectives. Thus, consumers may be at a disadvantage when seeking to make choices regarding products in foodservice establishments (or when choosing among establishments). Some stakeholders believe that providers do not have an incentive to provide information voluntarily, and thus that government intervention may be necessary to ensure that consumers have adequate access to product information.
- **Benefits Should Exceed Costs:** Public policy usually requires that the benefits of any action justify its costs. While it might be desirable to provide information to consumers about a product or service, the cost of doing so should be measured against the benefits that might accrue to consumers. If the benefits of providing that information are difficult to measure or are unknown—i.e., if consumers receive information and it is not clear what they do with it, if anything—then mandated action may be difficult to justify. Past cost-benefit analyses for food labeling have resulted in highly favorable cost-benefit ratios.
- Measurable Impact: Some stakeholders argue that government action should not be taken unless its impact can be measured with some degree of certainty. Others maintain that actions should be based on the best data available. Impacts that could be measured include: Do consumers make lower-calorie choices if calorie information is provided at the point of sale? Does that meal choice affect their overall caloric intake? How do cost information and nutrition information interact for consumers? If nutrition information is provided, how will that affect various revenues and market share? How will it affect product formulation, portion size, calorie density, and the mix of choices available on menus?
- **Precaution and Prevention:** When significant adverse health consequences are possible and may affect substantial segments of the U.S. population, actions should be taken on the basis of the best available data. As noted in the Institute of Medicine's 2004 report, *Preventing* Childhood Obesity: Health in the Balance, "[t]he obesity epidemic is a serious public health problem that calls for immediate action to reduce its prevalence as well as its health and social consequences. Therefore...actions should be based on the best available evidence—as opposed to waiting for the best possible evidence." Similarly, the American Academy of Pediatrics stated in a recent report on childhood obesity: "Evidence to support the

¹⁹⁰ See Golan, et al., "Economics of Food Labeling," 2001. The first page of this article notes that: "Government intervention in labeling in the United States has served three main purposes: to ensure fair competition among producers, to increase consumers' access to information, and to reduce risks to individual consumer safety and health."

¹⁹¹ Institute of Medicine, *Preventing Childhood Obesity*, 2004.

recommendations for prevention is presented when available, but unfortunately, too few studies on prevention have been performed. The enormity of the epidemic, however, necessitates this call to action...using the best information available." Estimating costs and benefits requires dealing with uncertainties (i.e., cost and benefit calculations can be rife with assumptions, biases, and uncertainties, though such estimates are made routinely and frequently guide policy decision-makers).

- Market Failure: The free, unencumbered market tends to under-provide objective information. The reason is that once someone pays to create information, it can be freely distributed among consumers beyond the control of the producer. As a result, interested consumers are frequently forced to make decisions about their calorie intake on the basis of imperfect information. The fact that free markets tend to under-provide objective information argues that there is an economic rationale for governments to require or provide the production and dissemination of information.
- Public Health: Obesity and overweight are pressing public health issues. Their
 consequences include early death and increased risk of the leading causes of death in the
 United States, including heart disease, cancer, and diabetes. These outcomes decrease the
 well-being and health of American citizens and increase the costs of health care. Thus, it is
 incumbent upon public health officials, business, and government to improve public health
 by providing nutrition information that will enable consumers to make more healthful
 choices.

The Forum's Recommendations

Forum participants in this section offer two recommendations regarding the provision of nutrition information for away-from-home foods.

Recommendation 4.1

Away-from-home food establishments should provide consumers with calorie information in a standard format that is easily accessible and easy to use.

Current Efforts

The availability of nutrition information regarding away-from-home foods has increased over the past ten years. According to a recent study of the 287 largest chain restaurants in the United States, 54% make at least some nutrition information available. Forty-four percent provide some kind of information, in a variety of formats, for the majority of their standard menu items. ¹⁹³ No

Page 76 of 134

¹⁹² American Academy of Pediatrics, "Prevention of Pediatric Overweight and Obesity: Statement of Policy," *Pediatrics* 12, no. 2 (2003).

¹⁹³ M.G. Wootan and M. Osborn, "Availability of Nutrition Information in Chain Restaurants in the U.S.," *American Journal of Preventive Medicine* 30: 266-268.

similar studies have been conducted for non-chain (or independently owned) dining establishments.

As discussed previously, evidence on how and why consumers use nutrition information is limited at present. (See Appendix I for a literature review on this topic.) Though the experience in away-from-home-foods may be different than for packaged foods, some argue that a key benefit of mandatory nutrition labeling on packaged foods has been the reformulation of existing products and the introduction of new nutritionally improved products.

Foodservice operators currently share with their customers many kinds of nutrition information, including numerical values, symbols, information about food allergies and sensitivities, and recommendations for specific dietary needs. The information shared and the format in which it is shared varies widely among different establishments. Some chains, such as Au Bon Pain and (soon) McDonald's provide the equivalent of a Nutrition Facts panel (like that on packaged foods) for menu items. Some provide carbohydrate information, others provide data on fat content, and others list total calories. In addition, great variability can exist among the outlets of a given company, depending upon the perceived interests of the client (e.g., hospital, museum, college) and the customer base (e.g., patients, tourists, young adults).

Of restaurant chains providing nutrition information, most (82%) provide information on several key nutrients for the majority of their menu items. 194 In an informal survey of the websites of nearly 40 restaurant chains, Forum participants found that the great majority provided a summary nutritional profile that included calories, calories from fat, total fat, saturated fat, cholesterol, sodium, total carbohydrates, dietary fiber, sugar, and protein. In addition, almost three-fourths of the sites offered trans-fat information for these same menu items. These nutrition facts are almost always expressed in grams per serving.

Of those restaurant chains that currently provide nutrition information, 86% use the company website as at least one means of doing so. 195 Foodservice venues also provide information in a number of ways in-store, both at the point of decision (e.g., though electronic kiosks, brochures, table guides, or server handhelds) and after the point of decision (e.g., via packaging, "nutrition receipts" on register tape, or tray liners). Cafeterias and grocery stores may use informational signs on, in, or near food counters, or next to self-serve items such as soups. A few establishments provide guidance on where to locate the information—for example, with a notification on a menu board directing customers to a brochure.

Operational Tips

Keystone Forum participants suggest the following operational tips and considerations.

Information should be provided in a manner that is easy for consumers to see and use as part of their purchasing and eating decisions. Consumers might view such information, for example, when standing at a counter, while reviewing a menu board, in a car when reading a drive-through menu, or when sitting down at a table reviewing a menu, table tent, or other

¹⁹⁴ Ibid.

¹⁹⁵ Ibid.

means of providing information. The means and location for providing nutrient information are discussed more fully in Appendix J.

- Information should be provided for any standard menu item offered on a regular and ongoing basis (i.e., offered daily or regularly for at least three months of the year) that is prepared from a standardized recipe, whether the item is an entire meal or a meal component (e.g., entire meals, appetizers, side dishes, desserts, beverages). Non-standard items, including daily specials and experimental items, may be exempted. The information should be provided for the different size offerings (i.e., small, medium, large) of each standard menu item. Of course, changes based on availability and recipes can still occur in standard items.
- Information should be provided for the standard menu item as usually offered for sale (i.e., the base product, in the portion size as offered for sale), since most means of providing information (with the notable exceptions of computer-based systems such as websites and electronic kiosks) cannot easily account for changes due to customization and special orders.
- Information should be accompanied by a caveat regarding variations owing to preparation, customization, server variability, and so forth.
- Single-store operations and small chains may not be able to provide nutrition information. Other foodservice venues, such as contract dining services, that have variations in sourcing and preparation, or that do not have standard menus, may also have difficulty providing information that is accurate, reliable, and consistent. For instance, where segments of the industry employ trained chefs (such as in fine-dining establishments and as compared to institutional cooks or foodservice workers), the chefs may prepare primarily by taste and feel and either not use, veer from, or disregard standardized recipes. Lack of standardized recipes and preparation, variations in management and operational control systems, and the cost of product analysis are potential obstacles for smaller operators. However, restaurants and other foodservice operators are encouraged to provide the information to the extent feasible, especially since some programs exist to support them in doing so. An example includes the National Restaurant Association's Ask Us! program, a voluntary, nationwide, branded effort to help restaurants provide nutrition information to interested customers.
- For more guidance on providing nutrition information, please see Appendices G and H from the FDA Obesity Working Group Report *Calories Count*, as well as the ORC Macro report on Restaurant and Food Labeling Focus Group Research. 196

Additional considerations for foodservice operators related to this recommendation include the following (see Chapter 3 for greater detail).

1.

¹⁹⁶ FDA, Calories Count, Appendix H ("Developing Effective Consumer Messages") and Appendix G (a reprint of FDA, Helping Consumers Lead Healthier Lives through Better Nutrition: A Social Sciences Approach to Consumer Information, Food Choices, and Weight Management, A Report from the Division of Market Studies (Rockville, MD: FDA, 2004)); and ORC Macro, Restaurant and Food Labeling Focus Group Research: Summary Report (Rockville, MD: FDA, 2003).

- Operators might indicate simple ways of making lower-calorie substitutions, to help consumers customize their meals with total calories in mind.
- Operators might use menu descriptions that include cooking method, ingredients, etc., which can help point out to consumers the lower-calorie options. For example: "Pan-seared skinless chicken breast with mango salsa served with chipotle grilled polenta."
- Operators might provide "standard" and "light" versions of standard ingredients and condiments, such as substituting salsa for sour cream, omitting cheese, and so forth.

Costs and Methods of Analysis

The cost of laboratory analysis for nutrition information ranges widely depending on the number of items on the menu and the costs charged by each laboratory. The cost to have one item analyzed for calories may be as low as \$100 but is estimated at about \$230 per item for more complete nutrition information (including saturated and trans fat, carbohydrates, and sodium). Since the number of items in larger-scale quick-service and casual dining establishments range from about 50 to more than 200, the cost for analyzing the entire menu initially would thus range from \$11,500 to \$46,000. PA sementioned previously, approximately half of chain restaurants already provide nutrition information on their websites or on in-store brochures. Thus, if this information were determined by laboratory analysis (as is the case for many chains), these companies would not necessarily incur any new costs for product testing in order to provide menu labeling. However, the analysis of new products and reformulations and the re-printing of materials would add additional and ongoing costs to operations. Operators newly adopting this recommendation would incur costs for posting this new information (e.g., on a website, menu, or menu board), in addition to the basic cost of determining caloric and nutritional content.

Software packages that allow smaller operations to estimate calories are also available. The typical software package costs around \$500 and uses pre-calculated information to estimate the caloric content of various products and meals. Though one could learn and use the software, often a company will hire a registered dietitian to use the software to calculate the nutrition information for products and meals. Dietitian rates vary widely depending on expertise and geography. Assuming the rate is \$100 per hour, and the time to do the calculations for a modest-sized menu (50 to 100 items) would be between 40 to 80 hours, the full initial cost of calculating caloric content using this method would be between \$4,000 and \$8,000. In addition to the basic laboratory analysis, further analysis of new products, reformulations, and base ingredient changes, and the re-printing of materials, would add additional and on-going costs to operations.

Standard methodologies for determining nutrient information such as calories have already been established for packaged foods for the NLEA. For compliance purposes under the NLEA, the FDA uses methods given in the most recent edition of *Official Methods of Analysis* of AOAC International, ¹⁹⁸ or, if no AOAC method is available or appropriate, by other reliable and appropriate analytical procedures. AOAC International's *Official Methods* volumes are updated annually with new or modified methods. The results of successful collaborative studies appear in

¹⁹⁷ Center for Science and the Public Interest, "Myth vs. Reality: Nutrition Labeling at Fast-Food and Other Chain Restaurants," www.cspinet.org/nutritionpolicy/Myth_vs_Reality_Nutrition_Labeling.pdf, accessed March 18, 2006. ¹⁹⁸ Formerly known as the Association of Official Analytical Chemistry.

the journal of AOAC throughout the year. ¹⁹⁹ The FDA has also posted guidance that discusses laboratory and statistical analyses for developing nutrition label values and addresses variability in reporting data for packaged food. ²⁰⁰

Multiple Solutions Necessary

Forum participants noted that the provision of nutrition information to away-from-home food customers is not the sole means by which consumers might more effectively manage their energy intake. Numerous factors contribute to weight gain and obesity. The interaction of these factors likely further complicates our understanding. Cause and effect in something as complex as people's choices and eating patterns is extremely difficult to discern. However, Forum participants noted that basic nutrition information provision is one of many actions that may help Americans to better manage weight gain and obesity and may provide incentive to companies to change the nutritional quality of their menus or specific menu items.

Considerations on Other Nutrition Information beyond Calories

Forum participants considered whether away-from-home food outlets should provide other kinds of quantitative nutrition information (i.e., beyond caloric content). A great many foodservice operators already choose to share comprehensive nutrition information with their customers.

Participants recognized that it is possible for an individual to maintain caloric balance and yet consume an unhealthy diet; therefore, additional nutrition information should be available to consumers. Some Forum participants raised the concern that providing calorie information in the absence of other nutrition information, such as that regarding nutrients of concern (i.e., calcium) and nutrients to avoid (i.e., saturated fat), could result in less-healthful food choices or unanticipated negative health consequences. However, addressing such a wide range of health considerations was outside the scope of the Forum. Although calorie information is most relevant to obesity prevention, several participants did favor the inclusion of additional nutrient information, especially for fiber and total, saturated, and trans fat, which may assist consumers with weight management or with health impacts that are associated with obesity. There was not consensus around which nutrients might be most appropriate, however.

Some Forum participants expressed interest in providing consumers with information regarding the energy density of menu items, but that concept is presently unfamiliar to the majority of consumers and many foodservice operators, and such information is not currently provided for packaged foods. Thus, participants did not recommend this means of reporting information.

Some participants also suggested including a reference point along with nutrition information, so that interested consumers would have a way of gauging how a menu item fits into their daily caloric needs. One suggestion was to provide totals—for calories and specific nutrients—that the

The Keystone Forum on Away-From-Home Foods—Final Report

¹⁹⁹ See also I.J. Jeon and W.G. Ikins, *Analyzing Food for Nutrition Labeling and Hazardous Contaminants* (New York: Marcel Dekker, Inc., 1995); and D.M. Sullivan and D.E. Carpenter (eds.), *Methods of Analysis for Nutrition Labeling* (Arlington, VA: AOAC International, 1993).

²⁰⁰ M.M. Bender, J.I. Rader, and F.D. McClure, *FDA Nutrition Labeling Manual: A Guide for Developing and Using Data Bases* (Rockville, MD: FDA, 1998). See www.cfsan.fda.gov/~dms/nutrguid.html.

average person should consume in a day, like the "daily values" on packaged food labels. But broad agreement did not exist within the group on this. Daily caloric intake recommendations vary according to weight, gender, physical activity levels, and other factors. For the time being, any reference points provided, for ease of consumer use and consistency across types of foodstuffs, should be the same as those provided for packaged goods under the NLEA.

Forum participants generally did not favor the use of health-related symbols (for menu sections or specific items) as a means of helping consumers to make informed choices. While symbols clearly associated with specific health considerations may be useful to some consumers, such as those on a specific disease-related diet, there is some evidence from market experience that health-related symbols on menus do not tend to encourage—and may even discourage—broader selection of those products. Health-related symbols: (1) can be confusing, since their definition is not always clear and can vary among establishments; (2) may not provide new information to customers; and (3) can be associated in consumers' minds with poor taste based on past experience with products that were promoted on the basis of health-related attributes but that were not made to be both healthful and delicious.

Considerations on the Means of Delivering Information

Forum participants differed substantially in their ideas regarding where and how basic nutrition information should be provided. Some stakeholders believe that nutrition information, at least for calories, must be provided at the point of sale on menus and menu boards, in order to offer adequate opportunity for the greatest number of consumers to make informed decisions, and without requiring additional effort by those interested in managing their energy intake. National polls, as noted above, show that about two-thirds of Americans support the provision of nutrition information on menus. Several participants noted, however, that this may detract from the dining experience, be costly to implement, slow down ordering times in establishments where quick service is an essential part of the value provided to customers, be difficult for consumers to read and/or comprehend, and may have unanticipated consequences in terms of sales, product substitution, and consumer behaviors. Forum participants did agree that information provided at the consumer's point of decision, wherever that might be, is most likely to be used and useful to the consumer. The group did not develop a consensus agreement on the means of providing nutrition information for away-from-home foods other than as described in this paragraph. An assessment of a wide range of means of delivery is included with this report as Appendix J.

Considerations Related to Children's Needs

Some Forum participants believed that nutritional information provided at the point of sale targeting children should contain information about nutrients other than just caloric content. There was also acknowledgment, however, that little evidence exists to indicate exactly what information should be provided for children and how this information might be utilized by parents as well as by older children and adolescents. Some felt the provision of caloric information has the potential for unintended negative effects on children, including conflicts between parent and child centering on food. In general, organizations such as the American Dietetic Association and the American Academy of Pediatrics have recommended specifically

against "calorie counting" for children, given the wide range of acceptable caloric intake in this population.

However, a recent Institute of Medicine report entitled *Food Marketing to Children and Youth: Threat or Opportunity?* specifically recommended that caloric content and other nutrient information be placed on restaurant menus for children.²⁰¹ Though the report has only indirect evidence to support this recommendation, it assumes that listing caloric content on the menu, accompanied by a marketing strategy to emphasize lower-caloric food and beverage choices for children, would have the desired effect of helping to manage the caloric intake of children. The context in which the information is provided—e.g., on the menu, in a pamphlet, or on a website—might affect the level and type of concern, where it exists.

Possible Unintended Consequences

Some Forum participants, while generally supportive of the provision of calorie information, raised concerns about unintended consequences (for consumers and operators). These unintended consequences included but were not limited to: (1) negative effects on company revenues; (2) possible negative perceptions of lower-calorie menu options (i.e., consumers may view lower-calorie items as less satiating or flavorful, thus actually decreasing the consumption of these products and meals); (3) consumers choosing a lower-calorie main item but increasing the purchase of side items, which could increase overall caloric intake; (4) emphasis on calories over other nutritional considerations; (5) increased, quantifiable costs for operators that outweigh the potential and more-difficult-to-determine benefits to consumers in managing weight gain and obesity, and (6) the potential provision of inaccurate information to consumers by operations not using standardized recipes.

Considerations on the Accuracy of Information

Owing to variance in preparation, sourcing, and other factors in the away-from-home sector, some are concerned that nutrition information in foodservice outlets cannot always achieve the same level of accuracy and reliability that consumers expect from that on packaged food labels. For certain types of venues, such as fine-dining establishments, menu and recipe variability and a culinary philosophy that does not include the use of standardized recipes may make the regular provision of nutrition information particularly difficult.

Nonetheless, NLEA standards are often used as a guide for away-from-home foods companies. Most Forum participants agreed that the information that is currently provided in the marketplace is accurate and reliable across companies in the away-from-home food sector. Though not an exact corollary, it is worth noting that in FDA surveys conducted in 1994 and 1996 to determine the percent of consistency between analyzed and labeled values for nutrients in packaged foods, consistency for calories was high—it was rated at 93% for both surveys (of approximately 300 different food products per survey). More recently, as a result of the FDA's label reviews and

The Keystone Forum on Away-From-Home Foods—Final Report

²⁰¹ Institute of Medicine, *Food Marketing to Children and Youth: Threat or Opportunity?* (Washington, DC: National Academies Press, 2005).

²⁰² Life Sciences Research Office (LSRO) and Federation of American Societies for Experimental Biology (FASEB), *Analytical Data and Label Review* (Rockville, MD: LSRO and FSAB, 1994); and LSRO and FASEB,

nutrient analysis (between October 2004 and December 2006), the FDA issued 56 warning letters addressing misbranding violations involving a variety of food products.²⁰³ Almost none of these misbranding violations involved inaccurate reporting of calories.

However, some stakeholders suggested that liability may be a factor inhibiting some foodservice companies from sharing nutrition information, either at all or in certain formats. Some companies may fear that they will be held legally accountable for inaccuracies that are due to variabilities inherent in a particular type of operation. No standards exist currently for setting a "margin of error;" thus operators are concerned that they may unduly open themselves up to liability. Some note that a retail operation's information accuracy is dependent on the accuracy of information from its suppliers, be it for single ingredients or pre-packaged foods or mixes. Thus, some suggest that the government could have an important role in sheltering responsible actors, ensuring consistency, and treating all players fairly by providing accuracy standards and methodologies across the industry. Others do not see evidence that liability is an inhibiting factor, given the wide and increasing availability of accurate nutrition information already in the marketplace.

Forum participants generally agreed that standards of accuracy need to be more flexible for away-from-home foods than for packaged foods, to reflect the greater variability in the away-from-home sector. Product substitutions by suppliers, even unbeknownst to the operator, as well as how the meal is constructed on site (both in what products are used and in what quantities) can contribute to variability.

Recommendation 4.2

Research by multiple sectors should be conducted on how consumers use nutrition information for away-from-home foods; how this information affects their calorie intake at that venue; how and why nutrition information affects operators' decisions, costs, and revenues; and unanticipated consequences.

There is a clear need for more research regarding how the provision of nutrition information, claims (such as "low calorie"), and symbols influence consumer preference and choice for away-from-home food consumption situations. Of particular concern is how, when, and why consumers use nutrition information and claims during their decision-making processes. More specifically, a better understanding is needed of the types of factors that moderate consumers' responses to the provision of nutrition information and claims for away-from-home foods.

Suggested research questions include the following.

• What types of individual consumer characteristics (e.g., age, gender, nutrition knowledge level, concern about weight) impact whether or not nutrition information is utilized when ordering away-from-home foods?

Consistency between Nutrition Label Information and Laboratory Analysis for 300 Food Products (Rockville, MD: LSRO and FSAB, 1997).

²⁰³ Personal communication, Anne Crawford, FDA, January 20, 2006.

- What type of information should be provided? Does the amount of information positively or negatively influence its usage?
- What types of nutrition information are most valuable to which segments of consumers?
- How do parents and children/adolescents use the calorie content and other nutrition information supplied at the point of sale for both children's menus and adult menus?
- What situational or environmental influences impact consumers' responses to nutrition information?
- Where is the point of decision for the range of away-from-home-foods consumers?
- How and where should information be provided, given the goals for providing such information? At point of sale, before sale, after sale for future purchases, etc.? Via menu board, brochure, table tent, poster, kiosk, etc.?
- If the information is accessed, how is it used?
- Under what circumstances is current behavior influenced and under what circumstances is future behavior influenced? For example, if consumers consume an extra 100 calories at lunch, will they eat a lighter dinner?
- How do nutrition information, claims, and symbols influence consumers' food choices, attitudes, and assumptions about the food item itself (such as perceived tastes and flavors) and impact their overall attitudes toward the restaurant?
- Is information on the caloric content of food items more likely to be used by the consumer when presented alone or when embedded in general nutrition content information?

Appendix A **Keystone Forum Supporting Participants, Information** Resources, and Project Staff

Affiliations are listed for the purpose of identification only. Participants were asked to represent their individual views throughout the Forum's deliberations.

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Page 86 of 134

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Informational Resources

The following individuals contributed to the Forum's deliberations in various ways. Some served as consultative advisors throughout the deliberations. Some served as formal participants, but elected not to support the report formally, generally due either to the nature of their organizations of affiliation or to the degree of their participation.

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Appendix B Research Regarding the Association of Away-From-Home Foods and Body Weight

The following is a brief annotated bibliography of sources regarding the association between away-from-home foods and overweight/obesity, as outlined in a presentation by Dr. Alice Lichtenstein of Tufts University at the April 26-27, 2005, meeting of the Keystone Forum on Away-From-Home Foods. Please note that the studies use different terms for away-from-home foods establishments, including "restaurants," "away-from-home food outlets," and "quick-service" or "fast-food" restaurants. Furthermore, the researchers may define these terms differently. Thus, one should consult the individual studies for more detail and clarity.

Binkley, et al. (2000)²⁰⁴

Using 1994 to 1996 data from the U.S. Department of Agriculture (USDA) Continuing Survey of Food Intakes by Individuals (CSFII), these researchers found that the source of food is a significant determinant of body mass index (BMI). This association was shown for both restaurants generally and fast-food outlets specifically. For females, the correlation was significant for fast-food outlets only, but for males, the correlation was significant for restaurants generally as well as fast-food outlets specifically.

Bowman, et al. (2004)²⁰⁵

Using CSFII data from 1994 to 1996 and the Supplemental Children's Survey from 1998, the researchers found that, for 4- to 19-year-olds, 30% of the sample population consumed fast food on a typical day. Those who ate fast food consumed more calories per gram of food and had poorer diet quality. The higher fast-food consumption was associated with males, older children, higher household income, non-Hispanic African-Americans, and residence in the South.

Bowman and Vinyard (2004)²⁰⁶

Using CSFII data from 1994 to 1996, the researchers found that 25% of adults reported eating fast food. The study found that such fast food provided greater than 33% of total calorie intake, and it found a positive association between fast-food consumption and overweight status.

²⁰⁴ J.K. Binkley, et al., "The Relation between Dietary Change and Rising U.S. Obesity," *International Journal of Obesity* 24 (2000): 1032-1039.

The Keystone Forum on Away-From-Home Foods—Final Report

²⁰⁵ S.A. Bowman, et al., "Effects of Fast-Food Consumption on Energy Intake and Diet Quality among Children in a National Household Survey," *Pediatrics* 113 (2004): 112-132.

²⁰⁶ S.A. Bowman and B.T. Vinyard, "Fast-Food Consumers vs. Non-Fast-Food Consumers: A Comparison of Their Energy Intakes, Diet Quality, and Overweight Status," *Journal of the American College of Nutrition* 23, no. 2 (2004): 163-168.

Clemens, et al. (1999)²⁰⁷

The study group was composed of premenopausal women. Groups were categorized as "low eating out" for meals consumed out five times or less per week and "high eating out" for meals consumed out six to thirteen times per week. The researchers found eating out frequency associated with higher intakes of calories, fat, and sodium.

Ebbeling, et al. (2004)²⁰⁸

In the first part of this study, the participants were instructed to eat as much or little as they desired in a one-hour period in a food-court setting. The participants, 13 to 17 years old, had large caloric intake (1652 calories), and overweight participants ate more than their leaner counterparts in both absolute terms as well as in estimated daily caloric requirements. In the second part of this study, caloric intake was determined for participants under "free-living" conditions for two days when fast food was eaten and not eaten. The researchers found that overweight adolescents consumed significantly more total calories on fast food days (almost 18% more). Lean adolescents had no significant difference in total calorie intake between fast food and non-fast food days.

French, et al. (2000)²⁰⁹

This three-year prospective intervention trial found that frequency of fast-food restaurant use was associated with higher caloric intakes and higher fat intake (as a percent of calories) and lower consumption of fiber and fruit. The frequency of fast-food restaurant use was also positively associated with younger women, those with lower income, and those with non-White ethnicity.

Guthrie, et al. (2002)²¹⁰

Using data from the 1977-78 Nationwide Food Consumption Survey and from the 1994-1996 CSFII, the researchers found changes in the source of calories consumed over time. Food prepared away from home (restaurants, schools, daycare, or other) increased from 18% to 34% of total calories. Meals and snacks prepared away from home contained more calories per eating occasion, and those meals and snacks were higher in fat and saturated fat and lower in fiber, calcium, and iron per calorie consumed.

Jeffery and French (1998)²¹¹

This study considered the correlation between fast-food intake and energy intake and body mass. (The study also looked at TV, VCR, and cable TV watching). Recruitment was done via the USDA Women, Infants, and Children program (WIC) for those not pregnant one year prior to or following WIC enrollment. Total calorie intake and BMI were positively associated with fast-food consumption.

²⁰⁷ L.H. Clemens, et al. "The Effect of Eating Out on Quality of Diet in Premenopausal Women," *Journal of the American Dietetic Association* 99 (1999): 422-444.

²⁰⁸ C.B. Ebbeling, et al., "Compensation for Energy Intake from Fast Food among Overweight and Lean Adolescents," *Journal of the American Medical Association* 291 (2004): 2828-2833.

²⁰⁹ S.A. French, et al., "Fast Food Restaurant Use among Women in the Pound of Prevention Study: Dietary, Behavioral, and Demographic Correlates," *International Journal of Obesity* 24 (2000): 1353-1359.

²¹⁰ J.F. Guthrie, et al., "Role of Food Prepared Away from Home in the American Diet, 1977-78 Versus 1994-96: Changes and Consequences," *Society for Nutrition Education* 34 (2002): 140-150.

²¹¹ R.W. Jeffery and S.A. French, "Epidemic Obesity in the United States: Are Fast Foods and Television Viewing Contributing?" *American Journal Public Health* 88 (1998): 277-280.

Lin, et al. (1996)²¹²

Using data from the USDA's 1989-91 CSFII and the Diet and Health Knowledge Survey, USDA researchers found that the foods children eat from fast-food and other restaurants are higher in fat and saturated fat and lower in fiber, iron, calcium, and cholesterol than foods from home.

Maddock (2004)²¹³

The researcher considered state-level data on the percent of the population that is obese, fast-food restaurants per square mile, and self-reported behaviors, from physical activity to fruit and vegetable consumption. The study found state levels of obesity to be inversely related to the number of residents per fast-food restaurant density and the number of square miles per fast-food establishment. Other factors associated with obesity were income, fruit and vegetable intake, and percentage population of African-Americans.

Manchino, et al. (2004)²¹⁴

The researchers used data from the USDA's 1994-96 CSFII and the 1994-96 Diet and Health Knowledge Survey. The researchers found that overweight and obese women go significantly longer intervals between meals than healthy-weight women, and receive more of their daily calories from fast-food restaurants.

McCrory, et al. (1999)²¹⁵

The study group was comprised of "healthy" men and women. Restaurant consumption averaged 7.5 times per month. After controlling for age and gender, frequency of restaurant consumption was associated positively with body fatness (as measured by underwater weights). The association was unaltered after controlling for education, smoking status, and alcohol intake. The association increased after controlling for physical activity.

Paeratakul, et al. (2003)²¹⁶

Using CSFII data from 1994 to 1996 and 1998, the researchers found that 37% of adults and 42% of children reported eating in fast-food establishments. On the basis of two nonconsecutive 24-hour diet recalls, adults and children who reported eating fast foods had higher intakes of calories, fat, saturated fat, sodium, and soft drinks and lower intakes of vitamins A and C, milk, fruits, and vegetables than people who did not eat fast food.

The Keystone Forum on Away-From-Home Foods—Final Report

²¹² B.H. Lin, et al., *Diets of America's Children: Influence of Dining Out, Household Characteristics, and Nutrition Knowledge*, Agricultural Economic Report #726 (Washington, DC: USDA, 1996).

²¹³ J. Maddock, "The Relationship between Obesity and the Prevalence of Fast-Food Restaurants: State-Level Analysis," *American Journal of Health Promotion* 19 (2004): 137-143.

²¹⁴ L. Manchino, et al., *The Role of Economics in Eating Choices and Weight Outcomes*, Agricultural Information Bulletin #791 (Washington, DC: USDA, 2004).

²¹⁵ M.A. McCrory, et al., "Overeating in America: Association between Restaurant Food Consumption and Body Fatness in Healthy Adult Men and Women Ages 19 to 80," *Obesity Research* 7 (1999): 564-571.

²¹⁶ S. Paeratakul, et al., "Fast-Food Consumption among U.S. Adults and Children: Dietary and Nutrient Intake Profile," *Journal of the American Dietetic Association* 103 (2003): 1332-1338.

Pereira, et al. (2005)²¹⁷

This study used data from the Coronary Artery Risk Development in Young Adults (CARDIA) study. The CARDIA study included 3,031 females and males from 18 to 30 years of age in 1985 and 1986, and it included a follow-up 15 years later. The analysis found that a change in fast-food frequency was positively associated with changes in body weight. Those who frequented fast-food restaurants more than two times per week at baseline and follow-up gained an additional 4.5 kg (about 10 pounds) over the 15 years and had a twofold greater increase in insulin resistance.

Satia, et al. (2004)²¹⁸

This study considered a cross-sectional sample of 658 African-Americans from 20 to 70 years of age in North Carolina. The study found eating in fast-food restaurants to be associated with higher total fat intake, higher saturated fat intake, and lower vegetable intake. Frequent eaters in such establishments were more likely to be younger, never married, obese, and/or physically inactive.

Schmidt, et al. (2004)²¹⁹

In a longitudinal, multicenter cohort study of 2,379 girls (ages 9 to 19), increased fast-food intake was associated with increased intake of energy, fat, and saturated fat (as a percent of calories).

Thompson, et al. $(2004)^{220}$

The researchers conducted a longitudinal growth study with girls 8 to 12 years of age at the baseline with a follow-up when they were 11 to 19 years of age. The study showed that, at baseline, eating at quick-service restaurants more often was associated with increases in BMI. This was most evident when quick-service frequency was two times per week or greater.

Zoumas-Morse, et al. (2001)²²¹

This study combined data from two populations: (1) 376 children, 7 to 11 years old, and (2) 435 adolescents, 12 to 17 years old. It found that the study subjects' largest consumption of calories took place in restaurants. Of almost 2,500 calories consumed per day, restaurants contributed 31.3% of the total calories, followed by home at 17.3% of calories. Other sources of food included—in order of contribution from higher to lower—school/daycare, friend's homes, other, and transit. The study found that children typically eat almost twice as many calories when they eat a meal at a restaurant (765 calories) compared to an average meal at home (425 calories). Children and adolescents also ate more energy from fat and saturated fat when eating at a restaurant compared to at home.

²¹⁷ M.A. Pereira, et al., "Fast-Food Habits, Weight Gain, and Insulin Resistance (The CARDIA Study): 15-Year Prospective Analysis," *Lancet* 365 (2005): 36-42.

²¹⁸ J.A. Satia, et al., "Eating at Fast-Food Restaurants is Associated with Dietary Intake, Demographic, Psychosocial, and Behavioral Factors among African Americans in North Carolina," *Public Health Nutrition* 7 (2004): 1089-1096.
²¹⁹ M. Schmidt, et al., "Fast-Food Intake and Diet Quality in Black and White Girls," *Archives of Pediatrics and Adolescent Medicine* 159 (2004): 626-631.

Adolescent Medicine 159 (2004): 626-631.

²²⁰ O.M. Thompson, et al., "Food Purchased Away from Home as a Predictor of Change in BMI Z-Score among Girls," *International Journal of Obesity* 28 (2004): 282-289.

²²¹ C. Zoumas-Morse, et al., "Children's Patterns of Macronutrient Intake and Associations with Restaurant and Home Eating," *Journal of the American Dietetic Association* 101 (2001): 923-925.

Appendix C Success Factors in Consumer Acceptance of Low-Calorie Innovations in the Away-From-Home Food Market

Compiled by Dave McKechnie and Brian Wansink Cornell University, Ithaca, NY

The following is a compilation of successful tactics in healthy food promotion that have been used by various segments of the foodservice industry recently. In each case study the market was analyzed by asking representatives of the relevant companies eight questions pertaining to the development, promotion, and success of their healthy products. While there seemed to be several common trends that led to success in each case, there were also some specific tactics that were used for certain market segments and that improved individual results.

Overview of the Case Studies

Nabisco

Introduced in 2004, Nabisco's 100-Calorie Packs were designed to provide great-tasting, better-for-you products that help consumers maintain sensible eating habits. The line featured new versions of some Nabisco classics, conveniently delivered in pre-portioned packages, each containing 100 calories and zero to three grams of fat per pack. The product line was considered a success due to positive responses from consumers, industry, and the media, leading to the brand reaching \$100M in sales in less than a year.

Family Dining Chain

The company analyzed in this case is a small- to mid-sized chain (with between 90 and 100 stores nationwide) specializing in Italian-influenced cuisine and family-friendly dining.

In 2004, the company began to "lighten up" its menu offerings, creating new dishes with lighter ingredients (in terms of calories and fat) and more of a Mediterranean flair. One of the chain's biggest successes has been the greater use of vegetables. All new entrees are now presented on the menu with vegetables rather than a starch (e.g., pasta or potatoes) as the standard accompaniment. Customers are explicitly given the option of substituting the starch back in, but roughly 90% of customers go with the vegetables.

Replacing the starch with vegetables has caused sales to increase by 10-15% on an item-by-item basis. Entrees with vegetables as a main focus have also been selling well. The chain's overall sales have gone up 4-5% during this period.

Grocery Chain

This grocery chain introduced a line of approximately 15 prepared food items (i.e., prepared on site), consisting largely of salads such as potato salads, pasta salads, curried brown rice chicken salad, black bean and mango salad, and lentil and split pea salads. The products were developed to be lower in fat by using fruit juices, vinegars, and nonfat and reduced-fat dressings and dairy products. The line also included some hot entrees such as vegetarian chili and salmon. Point-of-sale markers indicated products as "Eat for Health." However, the signage was inconsistent due to lack of maintenance at store level. After several months, the line was discontinued. Many of the items are considered successful, however, since sales initially met projections and the products are still provided in stores and selling reasonably well.

Lower-Fat Milk Consumption

The new products in this case study were 1% and 2% white and chocolate milk in 8-ounce plastic bottles. The products were introduced to two quick-service restaurant (QSR) chains (dubbed QSR A and QSR B) and one fast-casual restaurant chain. Sales soared when the repackaged milk debuted on menus; in restaurants overall, milk orders rose 10% in the timeframe.

- QSR A Sales doubled
- QSR B Saw a 15-fold increase from 65,000 units to 1 million units per week
- Fast-casual restaurant Saw a 5% increase

These results are particularly significant because overall milk sales have declined since the 1960s. Milk sales at QSRs A and B have been sustained and healthy since switching to the 8-ounce plastic bottles.

Seasons 52 Restaurant

Seasons 52 is a new fresh grill and wine bar in Florida that has great-tasting and satisfying meals with nothing on the menu over 475 calories. It's marketed as a "new kind of chain"—one that celebrates food and is not about deprivation or satisfying satiation. The restaurant has seasonally inspired menus that reflect the freshest products available and also offers terrific wines, which speaks to its upscale nature. The restaurant has received positive consumer and media reviews, which has been its most prominent measure of success so far.

Quick-Service Restaurant – Lower-Calorie Sandwiches

A QSR company began in the last five years marketing a line of lower-calorie sandwiches and promoting them as better (i.e., "healthier") choices. This period of time has corresponded with a big boom in the company's sales. It is difficult to know how much of this boom resulted from the marketing of those sandwiches, the product's attributes (taste, value), or the simultaneous redesign of stores. But the sandwich line is viewed internally as a sales success and is a big part of the chain's identity with consumers.

Analysis of Responses Received

The following are the questions asked of interviewees, followed by an analysis of the responses received.

How is the product or concept relevant to obesity prevention?

The first topic of interest when looking at these new healthy products and concepts was how they were developed to address obesity prevention. The most common technique for making the foods healthier was to adhere to nutritional guidelines set forth by respected organizations in the health industry.

Seasons 52 follows the recommendations for nutritional balance set forth by the National Institutes of Health and other respected organizations. These organizations place an emphasis on eating whole-food carbohydrates such as fruits, vegetables, and whole grains; beneficial oils, such as extra-virgin olive oil; and lean meat and fish, especially those high in omega-3 fatty acids. In another example, the grocery chain that introduced the line of lower-calorie prepared food items followed the health-claims criteria set forth in the federal Nutrition Labeling and Education Act. The family dining chain described their menu changes as "absolutely" lowering calorie levels for the chain's menu entrees—up to an estimated 15-20% reduction in calories across the board over two years. The changes don't necessarily affect portion size, just the choice of foods that are on the plate.

In terms of profits, both changing menu items to fit specific nutritional guidelines and individually deciding how to make dishes lower calorie and healthier have worked out favorably for these companies. The path that a business chooses in making their menu healthier has long-term effects on their positioning in the market. For example, if a company decides to strictly tailor its menu items to the recommendations of a certain health organization, then that will illustrate to the consumer that the company has made a firm commitment to providing healthy choices. But the process of creating those menu items and getting them validated takes a significant amount of time and cost, making the company less flexible in the short run. By contrast, self-designing healthy menus is a very adaptable strategy. Changes to menu items can be made virtually every day, putting the company in a very good position in a trend-conscious marketplace. The business is not able to make any solid nutritional claims using this approach, however, which could act as a deterrent to health-conscious consumers.

To decide which approach to take, a business must obviously determine in what type of marketplace it is positioned. Only after addressing this question will the business be able to decide whether it is worthwhile to invest in creating menu items according to specific nutritional guidelines, or if it would be more profitable to make its own changes to its products.

Other than taste, what do you think helped contribute to the success of this product or concept?

When asked what factors apart from taste made their new product or concept successful, the respondents' answers ranged from meeting the market demand to contemporary packaging. Nabisco felt that its new 100-Calorie Packs delivered a "lifestyle need for BFY [better-for-you] snacks in portion-controlled convenience." Nabisco used extensive consumer testing before the product line's launch in order to determine the name, packaging, advertising, public relations, and consumer promotions.

The lower-fat milk campaign used contemporary packaging to change the perception of the product in the consumer's eye. By replacing traditional paper cartons with attractive 8-ounce plastic bottles with appealing graphics, the restaurants were able to penetrate the most difficult segment of the milk market—children.

All of the companies interviewed emphasized how important it is to focus on factors other than the taste of the product and to view things through the consumer's eye. The amount of testing and number of factors that were looked at through the "lens of the consumer" differed greatly for each new product or concept analyzed. Companies seemed to be the most successful when they scaled their research and marketing efforts proportionally to the "size" of the product or concept. Companies adding a single product to a product line can focus on a single characteristic of that product (i.e., packaging, slogan, consumer trends). When a company decides to make a more significant change to its overall product set, however, the company must look at more factors through the consumer's eye—including every aspect of marketing, from packaging to promotions to media coverage—in order to ensure that the product will be successful. In short, companies cannot rely on the content of the product for it to become successful. The marketing mix is key, though companies must determine how much is needed for each specific product to succeed.

Do you think that any media, social, economic, or policy factors external to the product or concept influenced the success or failure of its launch?

Many of the industry representatives said they used trends external to the product itself to influence the launch of the product. When the QSR chain introduced its lower-calorie sandwiches, low-fat diets were still very popular among the public. The chain took advantage of this social trend and focused its advertising on the low fat content of its new products.

Nabisco responded to this question as follows: "The social, media, and policy environment played a role in this product's creation and success. At the time of the product launch [mid-2004] the issues of obesity and the desire to help consumers understand portion control were gaining prominence in all of these arenas."

The family dining chain also looked toward societal trends in tailoring their new products. The interviewee from this company felt that "as the younger generation grows older and is a few years into raising their own children, they're responding to new information about healthy eating for kids and families."

Businesses seemed to be the most successful when they took the current trends and directly implemented them into their new products in every fashion, from content to product names, packaging, and advertising. The case studies thus suggest there is no reason not to take advantage of current swings in consumer preferences. However, it also seems that companies must pick and choose their targets carefully. Society will continue to become more health-conscious in the foreseeable future, but new diets, health concerns, and taste trends are always emerging. In order to market their nutritious product lines effectively, companies need to identify sustainable ways of advertising them.

In short, companies should take advantage of current media, social, economic, and policy factors that could help launch their products, but they cannot rely on those trends to carry their product forward indefinitely. Research must be done into identifying long-range trends, and action plans need to be created that will link the new product to those trends.

How did you position and promote the new product or concept to your customers? What did the ads say?

The companies interviewed used several different techniques to position and promote their new products to customers. The QSR chain with the lower-calorie sandwiches slowly developed their advertising campaign based on reactions from the consumer. "The initial ads just advertised the exact fat content," they said, "6 grams of fat or less." The company then began to advertise its nutrition information in terms that were understandable to the consumer. They compared their products' nutritional information to that of competitors, and then stated the difference in calories in terms of physical exercise such as number of push-ups, etc. Then, in 2000, the company launched an ad campaign featuring a customer who had lost a significant amount of weight while eating a steady diet of the lower-calorie sandwiches. The company believes the ads worked because they featured a "regular guy" to whom people could relate.

Another technique used to promote these healthy products was to use carefully selected words and phrases on the packaging and menus. The aim was to *imply* healthiness without scaring consumers away by making the product seem tasteless and bland. Nabisco's print advertising campaign supporting the launch of the 100-Calorie Packs focuses on "The Joy of Snacking." The company said this "helped convey the notion that Better For You snacks can be fun, tasty, and fit into an active lifestyle and balanced diet." The company also noted: "From consumer research, the brand knew that price value was important; therefore, advertising also highlighted the per-

pouch piece count, which communicated the benefit that 100-Calorie Packs were tasty and satisfying."

The family dining chain felt that "customers do not respond well to promotions that are explicitly health-oriented." New or changed items haven't been referred to as "healthy," but instead have been pegged as "Mediterranean" or, above all, "fresh."

These two different approaches to the positioning and promotion of products resulted in extremely different effects on consumers. In one approach, the business comes straight out and tells the consumer that this product is different and better, and here's why. The information is designed to make the consumer evaluate and compare the product with the competitor's products and inevitably choose the new product based on their decision variables. With this approach, marketers must develop a set of reasons why the new product creates more value than a competitor's products, and then the entire marketing campaign must revolve around these identified points of difference. When this approach is done effectively—and the product has valuable content—consumers in the target market will recognize the merit of the product and eventually purchase it.

In the second approach, marketing tactics are implemented to affect the consumers on a much more basic level. This method concentrates on the use of catch phrases, brand recognition, and key words in the packaging and advertising of the product. Consumers are not intended to use this marketing information to make a well-thought-out decision to purchase a product, but instead to instinctively recognize certain words or symbols that convince them to buy a product. While this tactic is more subtle than the full-blown advertising campaigns of the first approach, it requires just as much research and work to get right.

What specifically did you do to make the food taste good and still be lower-calorie?

Businesses relied on creative yet simple ideas to make their food still taste good despite its healthy qualities. The QSR sandwich chain said, "When the lower-fat items were first introduced, they were plain meat and/or vegetable sandwiches. In 2000, the company started developing fat-free sauces to add more flavor, like honey mustard to go with ham."

Some businesses decided to use natural techniques to enhance the flavor of their foods. Most entrees and appetizers at Seasons 52 are either grilled or roasted over open-fire oak-burning grills that create great flavor without the need for heavy sauces. At the family dining chain, many vegetables (e.g., asparagus, broccoli, spinach) are offered in different ways— steamed and plain, sautéed in butter, with parmesan cheese, etc.—so customers can exercise their preferences.

The main choice of which technique to use in boosting flavor—e.g., specialty low-fat sauces or natural cooking techniques—depends upon the complexity of the dishes that are offered. When dealing with simple food items such as cold sandwiches and salads, it is hard to find a way to naturally develop more flavor in the ingredients. (When ham is sliced a different way it doesn't suddenly turn spicy!) Businesses that rely on simple and easy-to-prepare foods such as this may

need to develop low-calorie additives in order to create the flavor profile that will convince consumers to purchase the product.

On the other hand, higher-end restaurants and the prepared meals sections of grocery stores can use a chef's skills and knowledge to create flavorful products by cooking things different ways. For these types of businesses, it would be more valuable to invest time and money in training their chefs how to create great-tasting food without using fatty ingredients.

How did you communicate that the product was lower-calorie—or did you—without turning people off by making them think it wouldn't taste good?

All of the companies interviewed emphasized that choice of wording in the packaging was key. Nabisco says, "It's all in the name '100-Calorie Packs'—100 calories, coupled with additional key consumer points (0g trans fats; 3 grams fat or less, etc.). In addition, the trademark names delivered a taste expectation that helped counter any potential negative perceptions around goodtasting BFY products."

The family dining chain also was careful in the words it used to describe its newly renovated food choices. "Consumers themselves make the association between 'health' and promotional language like 'fresh,' 'Mediterranean,' and 'not deep fried,'" the chain's spokesperson said.

The key when deciding how to label a healthy product is to look at the consumer's mindset when he or she is deciding whether or not to buy the product. For instance, if a product is located in a grocery store, the consumer is probably thinking about value, portion size, and possibly the health characteristics of the product. The best way to encourage a consumer to buy a product in this situation would be to state the facts clearly and succinctly so that the questions running through the consumer's mind are answered.

A menu item at a restaurant needs to possess very different characteristics. When consumers are in a dining mindset they are not as focused on value, but instead they think of taste, portion size, and possibly health. Labeling must be much more subtle in this situation. Companies must find words and phrases that both convince consumers that the item will satisfy their expectations and also connote that the product has significant nutritional value.

How was the support (ads, sales force efforts, distribution, trade promotions, etc.) different than for other typical launches with which you are familiar?

Various techniques were used to support these product launches. Nabisco gave out free samples of the product so that consumers could verify the taste claims of the product for themselves. At the grocery chain, the company's Vice President for Consumer Affairs wrote about the product

line in her popular column in the chain's circulars. The QSR sandwich chain featured their print ads in health-related publications, in an attempt to penetrate the health-conscious market.

All of these techniques proved to be successful, and it shows that creative ways of product promotion must be identified in order for a product to reach its full potential. These companies took a look at what their new product's biggest obstacle to success might be, and they tackled it head on in their marketing campaigns. When developing a product in the health-conscious segment of the foodservice industry it is almost impossible to find a product that everyone will accept initially. For this reason, if a business is confident in a new product, the business must take an unbiased look at what its biggest challenges will be in getting the product out into the market, and then develop strategies that will allow the product to penetrate the shopping habits of target consumers and so succeed.

Appendix D Selected Social Marketing and Education Efforts Relevant to Consumer Behavior and Obesity Prevention

This appendix provides summary descriptions of selected social marketing and education campaigns undertaken by the federal government and civic organizations.

Selected Government-Sponsored Initiatives

This section describes three government-sponsored initiatives in some detail, and then lists additional programs by agency.

Dietary Guidelines for Americans²²²

The Dietary Guidelines for Americans (DGA), first published in 1980, provide science-based advice to promote health and reduce the risk for chronic diseases through diet and physical activity. The recommendations contained within the DGA are targeted to members of the general public who are over the age of two and living in the United States. The DGA form the basis of federal food, nutrition education, and information programs. By law, the DGA are reviewed, updated if necessary, and published every five years. ²²³ The DGA contain examples of two eating plans that consumers can follow to meet the recommendations, and consumers are encouraged to follow the recommendations wherever they make food choices.

The U.S. Department of Health and Human Services (HHS) published a *Toolkit for Professionals*, created from the DGA, for health education experts such as doctors and nutritionists. Included in this toolkit is a section called "Eating Out with the Guidelines," which consists of tip sheets to assist consumers in making more healthful choices when eating out and helping them to understand portion size control, among other things. 224 The HHS also published an educational consumer brochure titled Finding Your Way to a Healthier You: Based on the Dietary Guidelines for Americans, which contains recommendations with respect to eating "on the go.",225

²²² U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA), *Dietary* Guidelines for Americans 2005 (6th ed.) (Washington, DC: HHS and USDA, 2005).

²²³ Public Law 101-445, Title III, 7 U.S.C. 5301 et seq.

²²⁴ HHS and USDA, *Toolkit for Professionals* (Washington, DC: USDA, 2005). See www.health.gov/ dietaryguidelines/dga2005/toolkit/.

²²⁵ HHS and USDA, Finding Your Way to a Healthier You: Based on the Dietary Guidelines for Americans (Washington, DC: USDA, 2005). See www.health.gov/dietaryguidelines/dga2005/document/pdf/brochure.pdf.

"5 A Day for Better Health" Campaign²²⁶

The national 5 A Day for Better Health program, which was initiated in 1991, is a large-scale, public/private partnership between the vegetable and fruit industry, the U.S. government, and nonprofit organizations. Its goal is to increase the average per capita consumption of vegetables and fruit in the United States to five or more servings every day. The long-range purpose is to help reduce the incidence of heart disease, cancer, and other chronic diseases through dietary improvements. Another benefit of the program, however, is its potential to reduce obesity. The program's specific objectives are to increase public awareness of the importance of eating five or more servings of vegetables and fruit every day and to provide consumers with specific information about how to incorporate more servings of these foods into their daily eating patterns.

The private side of the partnership is coordinated by the Produce for Better Health Foundation, a nonprofit organization composed of approximately 1,000 members of the fruit and vegetable industry. The public side is coordinated by the Centers for Disease Control and Prevention (CDC). The goal of the 5 A Day program coincides with one of the national health objectives for the country, which encourages the population to eat five or more servings of vegetables and fruit each day, and is also consistent with all other national dietary guidance provided by the U.S. government. Major components of the program—including point-of-sale initiatives (in supermarkets and foodservice establishments), media efforts, community programs, and research—have created a breadth of focused activity designed to change behaviors.

The "VERB It's What You Do" Campaign²²⁷

VERB, a part of the CDC's efforts to help reduce the national incidence of youth overweight and obesity, is a national, multicultural campaign coordinated by the CDC to encourage children ages 9-13 ("tweens") to be physically active every day. Components of the effort include paid advertising, marketing strategies, and partnership efforts. The program's website includes informational resources to help parents and professionals who serve tweens to make regular physical activity enjoyable.

Results from the first year of the campaign's activities include the following. First, the program succeeded in narrowing the gap in physical activity between girls and boys, with a 27% increase in free-time physical activity sessions among girls and a 37% decline among least-active girls in high-dose communities. Second, tweens from lower-income (\$25,000) and lower-middle-income (\$25,000-\$50,000) households became more physically active, with a 25% increase in free-time physical activity sessions among lower-middle income households. And third, the program reached a 74% awareness level among tweens nationally.

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²²⁶ See www.cdc.gov/nccdphp/dnpa/5aday/.

²²⁷ See www.cdc.gov/youthcampaign/.

That is, in communities receiving a "high dose" of the intervention.

Additional HHS Programs

HHS

- Healthy Lifestyles/Obesity Prevention Campaign. Developed in partnership with the Ad Council, this campaign includes public service announcements and a website with lifestyle tips.²²⁹
- Steps to a HealthierUS.²³⁰ A program begun in 2003 to help Americans live longer, better, and healthier lives. One component involves efforts to reduce obesity and to address poor nutrition and physical inactivity, with a focus on identifying, supporting, and promoting programs that encourage small behavior changes. Through a five-year cooperative agreement program, states, cities, and tribal entities receive funds to implement chronic disease prevention efforts focused on reducing the burden of diabetes, overweight, and obesity.

Food and Drug Administration (FDA)

- The Power of Choice: Helping Youth Make Healthy Eating and Fitness Decisions. 231 Intended for after-school program leaders working with young adolescents. Developed by the FDA and the U.S. Department of Agriculture (USDA) Food and Nutrition Service.
- Consumer education on diet and healthy lifestyles:
 - o FDA Consumer magazine, containing articles on nutrition and other health-related issues²³²
 - o FDA Nutrition Education web postings (e.g., Facts about Weight Loss Products and Programs)²³³
 - o Issuance of papers on obesity and nutrition, including a paper on restaurant menus and menu claims regarding "low-fat" and "heart-healthy" foods

Indian Health Service (IHS)

Nutrition and Dietetics Training Program. 234 Provides a wide range of nutrition training to IHS, tribal, and urban program health professionals and paraprofessionals, including tribal cooks, community health representatives, nutrition professionals, registered dietitians, health educators, nurses, substance abuse program staff, and school staff.

 Centers for Disease Control and Prevention (CDC)
 Making It Happen: School Nutrition Success Stories.²³⁵ This joint product of the CDC and the USDA tells the stories of 32 schools and school districts that have implemented innovative strategies to improve the nutritional quality of foods and beverages offered and sold on school campuses. The most consistent theme emerging from these case studies is that students will buy and consume healthful foods and beverages—and schools can make money from healthful options.

²²⁹ See www.smallstep.gov.

²³⁰ See www.healthierus.gov/steps/.

²³¹ See www.fns.usda.gov/tn/Resources/power of choice.html.

²³² See www.fda.gov/fdac/default.htm.

²³³ See www.cfsan.fda.gov/~dms/wgtloss.html.

²³⁴ See www.ihs.gov/MedicalPrograms/Nutrition/.

²³⁵ See www.fns.usda.gov/tn/Healthy/execsummary makingithappen.html.

National Institutes of Health (NIH)

- Strategic Plan for NIH Obesity Research. 236 Includes investigation of intervention programs.
- Obesity- and nutrition-related information via MEDLINE, ²³⁷ primarily through links to relevant research studies.
- Special applications of the National Heart, Lung, and Blood Institute—Portion Distortion²³⁸ and Menu Planner.²³⁹

Office of Public Health and Science

The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity²⁴⁰

Additional USDA Programs

Center for Nutrition Policy and Promotion

- MyPyramid.²⁴¹ A widely recognized nutrition education tool that translates nutritional recommendations into the kinds and amounts of food to eat each day. The MyPyramid Tracker is an online dietary assessment tool that includes nutrition messages and evaluates dietary intake as compared to the Food Guide Pyramid. The Tracker also includes recipes and tips for healthy eating.
- Food and Nutrition Information Center (FNIC).²⁴² The website includes sections on dietary guidelines, the food pyramid, food composition, dietary supplements, food safety, and healthy school meals. The FNIC's mission is to collect and disseminate information about food and human nutrition.

Selected Civic-Sector Programs

The Corner Store Campaign²⁴³

The Food Trust—a nonprofit organization aimed at improving access to healthy food—is conducting a "Corner Store Campaign," a program that seeks to reduce the incidence of dietrelated disease and obesity by improving the snack food choices made by adolescents in corner stores. The Corner Store Campaign uses social marketing and education to increase demand for healthy snacks, works with the food industry to increase the availability of healthier choices in stores, and promotes participation in the school meals programs.

²³⁶ See www.obesityresearch.nih.gov/About/strategic-plan.htm.

²³⁷ See health.nih.gov/search.asp?category_id=29 and www.nlm.nih.gov/medlineplus/.

²³⁸ See http://hin.nhlbi.nih.gov/portion/.

²³⁹ See http://hin.nhlbi.nih.gov/menuplanner/menu.cgi.

²⁴⁰ See www.surgeongeneral.gov/topics/obesity/calltoaction/CalltoAction.pdf.

²⁴¹ See www.mypyramid.gov/.

²⁴² See www.nalusda.gov/fnic/.

²⁴³ See www.thefoodtrust.org/php/programs/corner.store.campaign/php.

The program's Snack Smart social marketing campaign is currently working with specific stores in Philadelphia. Snack Smart marketing materials have been placed on refrigerator doors, snack racks, and the front doors and windows of each participating store. A Snack Smart Snack Guide with pictures of all snacks that meet specific criteria was placed on counters and walls or hung from ceilings. The Snack Guide provides kids with a clear and easy way to determine which are the healthier snacks and beverages.

The Corner Store Campaign also includes a Healthy Community Stores National Network, a national network of programs and institutions that are working to improve the availability and promotion of healthy food choices through food stores, particularly to disadvantaged and lowincome populations.

"1% Or Less" Campaign²⁴⁴

The 1% Or Less campaign is a health education program that aims to reduce saturated fat consumption by encouraging adults and children over two years of age to switch from drinking whole or 2% milk to 1% or fat-free (skim) milk. Rather than encouraging people to overhaul their entire diet or lifestyle all at once, the campaign focuses on this concrete and implementable message.

The Center for Science in the Public Interest—a Washington, DC-based nonprofit organization—has sponsored numerous 1% Or Less campaigns in communities nationwide. 1% Or Less campaigns can include:

- news coverage and paid ads on television, the radio, and billboards, and in newspapers;
- milk taste tests and nutrition presentations at supermarkets, worksites, schools, churches, and other community organizations;
- signs in supermarket dairy cases that promote low-fat milk; and
- school activities and contests.

Over the course of the seven-week pilot campaign in Clarksburg, West Virginia, low-fat milk intake doubled—from 18% to 41% of supermarket milk sales. These results held a year after the campaign had ended. The total cost of the campaign was about 22 cents per person. ²⁴⁵

Active for Life Campaign Demonstration Project²⁴⁶

The AARP conducted an "Active for Life Campaign," a social marketing project aimed at increasing the physical activity of people aged 50 and older. Funded under the Robert Wood Johnson Foundation's Active for Life program, the campaign was conducted in two demonstration sites—Richmond, Virginia, and Madison, Wisconsin—from 2002 through 2004. The AARP worked with a range of partners in these communities.

²⁴⁴ See www.cspinet.org/nutrition/1less.htm.

²⁴⁵ B. Reger, et al. "1% or Less: A Community-Based Nutrition Campaign," *Public Health Reports* 113 (1998): 410-

²⁴⁶ See www.activeforlife.info/default.aspx.

The goal of the Active for Life Campaign was to increase awareness of the benefits of physical activity and increase physical activity levels in target populations. The campaign promoted the specific exercise goal for older adults of moderate physical exercise for at least 30 minutes a day, five days a week.

The marketing communications included paid advertising on television and the radio and in print media. Direct mail to AARP members also encouraged participation in Active for Life activities. Project staff developed community resources guides, a handbook, and a coordinators' guide for partners involved in the campaign.

The results of these marketing communications were as follows.

- At six months, a survey found small positive changes in older adults' awareness of and attitudes toward exercise in the two pilot sites, along with preliminary indications that behavior was beginning to change.
- One year after the launch, the survey indicated that the campaign was having measurable effects on the 50-and-older populations in both Madison and Richmond. Both cities showed modest increases in overall rates of physical activity among those 50 and older and higher rates of participation in community-based exercise events than was the case prior to the campaign. However, there was a relatively low recall of Active for Life advertising in the two cities and an absence of any change in residents' reported exposure to exercise information.
- Two years after the inception of the Active for Life campaign, adults 50 and older in Madison maintained modest behavioral and knowledge changes. But the positive changes evident in Richmond after one year were no longer evident after two years.

Appendix E Summary of Key Government Efforts to Collect Data on Consumer Behavior and **Away-From-Home Foods**

This appendix summarizes the federal government's efforts to collect data on consumer behavior and away-from-home foods. These efforts have been and are being conducted by agencies within the U.S. Departments of Heath and Human Services, Agriculture, Labor, and Education.

U.S. Department of Health and Human Services, **Centers for Disease Control and Prevention**

National Health and Nutrition Examination Survey

The National Health and Nutrition Examination Survey (NHANES) is a program of studies designed to assess the health and nutritional status of adults and children in the United States. The survey is unique in that it combines interviews and physical examinations. The NHANES program began in the early 1960s and has been conducted as a series of surveys focusing on different population groups or health topics. In 1999, the survey became a continuous program that will have a changing focus on a variety of health and nutrition measurements to meet emerging needs. The survey examines a nationally representative sample of about 5,000 persons each year. These persons are located in counties across the country, 15 of which are visited each year.

The NHANES detailed interview includes demographic-, socioeconomic-, dietary-, and healthrelated questions. The examination component consists of medical and dental examinations, physiological measurements, and laboratory tests administered by medical personnel.

NHANES included the following question specifically related to away-from-home food consumption in its 2001-2002 survey questionnaires:

On average, how many times per week {do you/does sample person} eat meals that were prepared in a restaurant? Please include eat-in restaurants, carry-out restaurants, and restaurants that deliver food to your house. ("Meals" mean more than a beverage or snack food like a candy bar or bag of chips.)

United States Department of Agriculture (USDA), Food Surveys Research Group²⁴⁷

What We Eat in America

What We Eat in America is the dietary interview component of NHANES. As a precaution to protect the confidentiality of survey participants, single-year data from NHANES are not released for public use. For that reason, only Day 1 interview data are included in the present release. Neither the data collected on Day 2 in What We Eat in America 2002 nor Day 1 information that was only collected in 2002 (e.g., the place where each food was obtained) will be publicly released. Restricted data, such as those just mentioned, may be made available at the Research Data Center located at the National Center for Health Statistics (NCHS) headquarters in Hyattsville, Maryland. A research proposal for using the restricted data must be submitted to the NCHS for review and approval.

Continuing Survey of Food Intakes by Individuals

The 1994-96 and 1998 Continuing Survey of Food Intakes by Individuals (CSFII) collected information on the following topics, among others.

Food- and nutrient-related variables:

- Two nonconsecutive days of dietary intake using in-person, 24-hour recalls
- Food intakes in grams: by food item and by food groups and subgroups defined by the USDA's Agricultural Research Service. Intakes of food energy and 52 dietary components (including 19 individual fatty acids).
- Intakes of food energy and 15 nutrients as percentages of the 1989 RDAs

Sources of food:

- Where was the item obtained: store, restaurant, fast-food outlet, etc.
- Was the food item eaten at home?
- Was the food item ever at your home before you ate it?

Food shopping practices:

- Amount spent at grocery stores, on nonfood items, at specialty stores, and at fast-food or carryout places for food brought into the home
- Amount of money spent for food bought and eaten away from home

²⁴⁷ See www.ars.usda.gov/main/site_main.htm?modecode=12-35-50-00.

U.S. Department of Health and Human Services, Food and Drug Administration (FDA)

FDA Health and Diet Survey

The FDA's Health and Diet Survey (HDS) is a periodic telephone survey conducted by the FDA's Center for Food Safety and Applied Nutrition. Its purpose is to measure and monitor public awareness, knowledge, attitudes, and reported behavior related to food and nutrition. Topics in previous surveys have included food labels, fats, and dietary supplements. Data have been used to meet the FDA's information needs on these topics and to evaluate national programs such as the National Cholesterol Education Program. ²⁴⁸

The HDS includes the following questions regarding meals prepared in restaurants:

- First of all, think about all of the meals you eat in a typical seven-day week. Meals include breakfast, lunch, and dinner. About how many meals do you eat in a typical week?
- About how many of the (number reported above) meals you eat in a typical week are prepared in a restaurant? Please include eat-in restaurants, carry-out restaurants, and restaurants that deliver food to your house.

U.S. Department of Labor, Bureau of Labor Statistics

American Time Use Survey²⁴⁹

The American Time Use Survey (ATUS) measures the amount of time people spend doing various activities, such as paid work, childcare, volunteering, commuting, and socializing. The ATUS is a nationally representative sample drawn from households completing their final month of interviews for the Current Population Survey. The ATUS uses computer-assisted telephone interviewing to conduct the survey.

Potential data sources include:

- 1. Records activity. For example, people identify the time spent in the following activities:
 - a. Sleeping
 - b. Grooming (self)
 - c. Watching TV
 - d. Working at main job
 - e. Working at other job
 - f. Preparing meals or snacks
 - g. Eating and drinking

²⁴⁸ See www.cfsan.fda.gov/~comm/crnutri.html.

²⁴⁹ See www.bls.gov/tus/home.htm.

- h. Cleaning kitchen
- i. Doing laundry
- j. Grocery shopping
- k. Attending religious services
- 1. Paying household bills
- m. Caring for animals and pets
- 2. Simultaneous activities can be recorded (i.e., eating and watching TV).

While away-from-home foods are not part of the activity question, a follow-up question helps identify location. For example, the respondent would be asked, "Where were you while eating and drinking?" Answers could include:

- 1. Home or yard
- 2. Workplace
- 3. Someone else's home
- 4. Restaurant/bar
- 5. Place of worship
- 6. Grocery store
- 7. Other store/mall
- 8. School
- 9. Outdoors away from home
- 10. Library

If the respondent has not identified any time spent eating or drinking, there is a prompt to state, "You did not report any eating or drinking yesterday. Did you do any eating or drinking yesterday as your main activity?" If the respondent answers yes, then the time diary is edited.

U.S. Department of Education, **National Center for Education Statistics**

Early Childhood Longitudinal Study²⁵⁰

Kindergarten Cohort

The Early Childhood Longitudinal Study, Kindergarten Class of 1998-99 (ECLS-K) is an ongoing study that focuses on children's early school experiences beginning with kindergarten and following children through 12th grade. The ECLS-K provides descriptive information on children's status at entry to school, their transition into school, and their progression through 12th grade. The longitudinal nature of the ECLS-K data enables researchers to study how a wide range of family, school, community, and individual factors are associated with school performance.

²⁵⁰ See http://nces.ed.gov/ecls/.

The 5th-grade year includes a child food consumption questionnaire, but does not differentiate foods consumed by location. Questions are asked about food purchased at school.

Birth Cohort

The birth cohort of the Early Childhood Longitudinal Study (ECLS-B) looks at children's health, development, care, and education during the formative years from birth through kindergarten entry. It is comprised of a nationally representative sample of 14,000 children born in the year 2001.

The parent interview includes questions regarding the frequency of participating in certain activities with the child, including eating at a restaurant. A sample question is:

- 1. In the past month, how often did you do the following things with {CHILD}?
 - a. Play chasing games?
 - b. Play with games or toys indoors with {CHILD} {and {TWIN}}?
 - c. Go to a restaurant or out to eat with {him/her/them}?
 - d. Take {him/her/them} outside for a walk or to play in the yard, a park, or a playground? Was it more than once a day, about once a day, a few times a week, a few times a month, rarely, or not at all?

Appendix F The Design and Focus of **Needed Consumer Research**

The Forum proposes the following design elements and substantive questions to guide the development of needed consumer research.

Key Design Elements

For the purposes of gathering and assessing data, consumers should be segmented according to important demographic and behavioral variables, such as:

- Age
- Sex
- Education
- Income (including disposable income for food)
- Ethnicity
- Geographic location
- Body mass index
- Family size and ages of children
- How often they frequent foodservice venues (including by total visits and by type of venue)
- Whether they follow particular weight-control practices
- Whether they maintain a diet due to a particular disease
- Whether they use nutrition information in deciding what or how to eat
- Who in the household most often makes decisions regarding food choice
- Amount of time spent by household members in school and daycare

The research approaches employed might depend largely on quantitative methods for understanding behavioral choices and environmental influences. However, innovative qualitative methods may help to identify immediate determinants of choice of eating venue, and choices once inside a venue. Methods such as focus groups may be useful in generating lists of barriers to healthy eating or reasons why one venue is chosen over another, or for assessing consumer response to messages. The results could then be used to generate items for designing quantitative measures, such as survey instruments for use with large target populations. Research should be designed to identify repetitive patterns of behavior that contribute to obesity, so that once an intervention is designed, consumers will receive a sufficient "dose" of it.

Key Questions to Be Addressed through Further Research

Forum members propose that several important questions need to be addressed through consumer research and analysis, as follows.

1) Understanding what choices consumers are making

- Who is ordering what? What are they paying for it?
- Where are they buying it?
- How they are eating it (e.g., sharing, eating some and saving some for later)?
- Where are they eating it (e.g., in store, at home, in car, elsewhere)?
- What is the nutrient content?
- Who is buying "healthy" foods (or at least lower-calorie options)? New customers or previous ones?
- How does one meal occasion affect the rest of the day/week? How, if at all, do consumers compensate?
- Is it important to distinguish how adults behave when buying for themselves vs. parents buying for children?

2) Understanding why people are making those choices—i.e., the drivers of food choice and eating behavior

- What are the determinants of where consumers choose to go?
- What is the relative importance of lower-calorie options in choice of restaurant (compared to convenience, value, etc.)?
- What drives specific food choices once a venue has been selected?
- What psychological mechanisms drive food consumption?
- How do convenience and availability influence the consumption of desired "healthful" foods?
- What unique needs are being fulfilled by away-from-home foods as opposed to food prepared at home?
- Are there identifiable barriers that discourage healthy energy intake?
- Why do some consumers fail to make use of their own knowledge or beliefs regarding how they should eat to manage their weight?
- In what forums can education take place (schools, places of business, other)?
- Does more choice lead to eating more calories?
- What do the data show about behavior patterns of individuals who successfully maintain healthy energy-intake levels and healthy weight? Are their knowledge and skills transferable to other individuals? (For example, does eating alone, at one's desk, or while driving increase consumption of calories?)

3) Understanding how to motivate and equip consumers through marketing and education

- What do consumers say are motivating factors in changing their behavior?
- What can be learned anecdotally from product innovations over the past five years that have successfully and positively changed, or have failed to change, diet- and nutritionrelated attitudes and behaviors? What worked, over what timeline, and why?
- What inhibits consumers who already know what they "should" be doing or eating from transforming that knowledge into action?
- Since virtually everyone has difficulty estimating serving sizes accurately, which methods would be most successful for teaching individuals about appropriate portions?
- What alternative "value proposition" might successfully appeal to consumers while being consistent with healthy weight management?

4) Understanding consumer acceptance of product innovations relevant to weight management

- What is the best way (or ways) to promote customer acceptance of new/changed products?
- How can low-calorie and less-calorie-dense options best be marketed to different population segments?
- How do consumers respond to changes in portion size, greater choice of portion size, and changes in calorie density? What are the thresholds beyond which consumers notice such changes?
- What kinds of unpublicized nutrition changes can be effective with consumers? What are the barriers to/opportunities for silent change?
- Under what circumstances can fruits and vegetables be substituted successfully for more-calorie-dense and/or less-nutrient-dense items?
- How do consumers respond to greater choice of portion size, visual cues to help them gauge how much they've eaten, and lower-calorie plate composition and menu-pairing options?

Appendix G Summary of Survey Results

The Keystone Forum's Products, Menu Items, and Meals Work Group developed an informal, internet-based survey that was administered through the efforts of individual work group members who volunteered to share the survey with their colleagues. Nearly all of those participating in the survey were from the on-site/contract-feeding sector of the away-from-home foodservice industry. Because this did not reflect an adequately broad sample, Forum participants did not draft specific recommendations based on the results of the survey. Instead, the group agreed that an additional survey conducted outside of the purview of the Forum would be appropriate and helpful, as evidenced by Recommendation 3.4 in Chapter 3. What follows is a brief description of the Forum's survey and the summary of results.

Overview of the Survey

The purpose of the survey was to gather information from chefs and restaurant owners about their experiences helping customers to manage their weight and health, particularly via product reformulation and innovation. Individual restaurateurs' experiences with refashioning dishes and menus is often not disseminated and has not crossed over into academic research, regulatory policy, or public health practice; this survey was intended to open that pathway.

The survey was designed to cover the following areas:

- 1) Factors influencing the success of healthful items
- 2) How the industry currently makes healthy menu modifications
- 3) Effective ways to promote changes
- 4) Barriers to introducing healthy items
- 5) Restaurateurs' perceptions of factors that influence body weight
- 6) Demographic information

By collecting this information from a broad array of chefs, restaurant owners, managers, and others across the spectrum of industry sectors, Forum participants believe that researchers, public policy officials, and industry will gain a better understanding of what changes the restaurant industry might be encouraged to undertake in the future. This type of information could provide much-needed guidance to the industry as they increasingly look for ways to help consumers manage their weight.

Summary of Results²⁵¹

Five areas of inquiry were used to assess the best practices of foodservice providers in helping customers achieve or maintain a healthy weight. First, respondents were asked what factors and

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²⁵¹ Thanks to Collin Payne, PhD, Cornell University, for his work in compiling the survey results.

emphases would lead to a successful healthy menu item. Second, respondents were asked to indicate what, if any, modifications of an existing menu item (or parts of a menu item) could be successful in helping customers achieve or maintain a healthy weight. Third, respondents were asked what they thought were effective ways to promote menu items that were intended to help customers achieve or maintain a healthy weight. Fourth, respondents were asked about the perceived barriers to offering a greater number of menu items that help customers achieve or maintain a healthy weight. Lastly, respondents were asked about their knowledge of factors that have an influence on body weight. The results of each area of inquiry are discussed in turn below, followed by tables providing more detail.

Area 1. What Factors Influence the Success of a Healthy Menu Item?

"Taste" was the highest-rated response for foodservice providers in terms of the factor and emphasis used for successful, healthy menu items. "Value," "positioning" (e.g., health vs. taste vs. freshness), and "freshness" were the respective factors and emphases rated as next important and successful. "Advertising" and "healthy" were rated as the respective least important and least successful of all factors and strategies.

Area 2. How Would You Make Healthy Menu Modifications?

"Actively promote changes," was rated more highly as a way to promote changes to menu items than "make the changes without active promotion," and "introduce a new menu item," was rated more highly than "modify/change an existing menu item." "Reduce fat," "add vegetables," and "add fruit" were the highest-rated strategies used to modify existing menu items to be healthier. In contrast, "add fiber," "reduce carbohydrates," and "reduce protein" were the lowest rated. "Sides," "entrees," and "beverages" were rated as the easiest courses or meal parts to modify to be healthier, while "bundled meals," "appetizers," "snacks," and "desserts" were rated as the most difficult.

Area 3. What Are the Most Effective Ways to Promote Changes?

"Other on-site materials" (e.g., tray inserts, table tents, brochures, etc.), "menus," and "menu boards" were the highest-rated effective ways to promote healthy menu items, while "websites," "print ads," and "TV/radio ads" were the lowest rated.

Area 4. What Are the Barriers to Introducing Healthy Items?

"Staff nutrition knowledge," "consumer preference," and "staff skill and knowledge" were the highest-rated barriers to offering a greater number of healthy menu items, while "operational challenges," "ingredient pricing," "time," and "ingredient availability" were the lowest rated.

Area 5. Which Factors Most Influence Body Weight?

"Calories consumed," "total fat consumed," and "carbohydrates consumed" were the highestrated influences on body weight, while "protein consumed," "water consumed," and "fiber consumed" were the lowest.

Detailed Survey Results

Survey respondents were asked to use a scale of 1 to 9, wherein 9 was "very important" and 1 was "not at all important."

Area 1. What Factors Influence Success?

Table 1.

Below are factors that might determine the success of menu items to help customers reduce or maintain a healthy weight. In your experience, please rate how important each is to the		Chef	Manager	Other	
success of this menu item.	All	(n = 37)	(n = 62)	(n = 12)	F
How important is taste?	8.6	8.6	8.5	8.6	0.1
How important is value?	7.5	7.6	7.6	7.5	0.0
How important is positioning (e.g., health versus taste versus					
freshness)?	7.2	7.2	6.9	7.7	1.5
How important is advertising?	6.8	7.0	6.6	6.9	0.7

- Taste was the single most important rated factor in the success of a healthy menu item.
- Advertising was the single least important rated factor in the success of a healthy menu item.
- There were no significant differences between comparison groups in ratings.

Table 2.

Please rate how successful you think each of the different types		Chef	Manager	Other	
of emphases would be for this item.	All	(n = 37)	(n = 62)	(n = 12)	F
A Taste-related emphasis?	8.2	8.0	7.9	8.6	2.2
A Freshness emphasis?	8.0	8.2	7.9	8.0	0.6
A Healthy emphasis?	6.7	6.8	6.8	6.5	0.2

- A taste-related emphasis was rated the single most successful.
- A healthy emphasis was rated the single least successful.
- There were no significant differences between comparison groups in ratings.

Area 2. How Would You Make Healthy Menu Modifications?

Table 3.

1401001					
Suppose you are modifying an existing menu item to help customers achieve or maintain a healthy weight. Please rate		Chef	Manager	Other	
how you would promote the changes.	All	(n = 37)	(n = 62)	(n = 12)	F
Actively promote the changes	7.3	7.8	7.9	6.3	4.2
Make the changes without active promotion	3.4	3.5	2.8	4.0	1.9

- Respondents rated "actively promoting changes," in contrast to "making changes without active promotion" as the better strategy for promoting changes to an existing item to make it healthier.
- "Chefs" and "managers" rated "actively promoting the changes" as a significantly more successful strategy than the "other" category. ("Other" includes nutritionists and others.)

Table 4.

Tubic ii					
Suppose you were thinking of modifying an existing menu item or of launching a new menu item that was intended to help customers achieve or maintain a healthy weight. Please		Chef	Monogor	Other	
neip customers achieve of maintain a hearthy weight. Please		Chei	Manager	Other	
rate how successful you think each option would be.	All	(n = 37)	(n = 62)	(n = 12)	F
Introduce a new menu item	7.8	7.6	7.9	8.0	.71
Modify/Change an existing menu item	5.6	5.9	6.1	4.9	1.8

- "Introducing a new menu item," in contrast with "modifying/changing an existing menu item," was rated as a better option for helping customers achieve or maintain a healthy weight.
- There were no significant differences between comparison groups in ratings.

Table 5.

When modifying an existing menu item to help customers achieve or maintain a healthy weight, please rate how successful you think the following strategies would be.	All	Chef (n = 37)	Manager (n = 62)	Other (n = 12)	F
Reduce fat	7.2	7.4	7.0	7.3	0.7
Add vegetables	6.7	7.2	6.8	6.1	3.4
Add fruit	6.3	6.3	6.3	6.2	0.0
Add fiber	5.9	5.9	6.0	5.8	0.1
Reduce carbohydrates	5.7	6.0	6.3	4.9	2.6
Reduce protein	3.8	3.9	3.9	3.5	0.2

- Respondents rated "reducing fat" as the single most important strategy in helping customers achieve or maintain a healthy weight.
- Respondents rated "reducing protein" as the single least important strategy in helping customers achieve or maintain a healthy weight.
- "Chefs" and "managers" rated "adding vegetables" as a significantly more successful strategy than the "other" group. ("Other" includes nutritionists and others.)

Table 6.

How easy is it to modify each of the following courses or meal parts so they help customers achieve or maintain a healthy weight?	All	Chef (n = 37)	Manager (n = 62)	Other (n = 12)	F
Sides	6.9	6.9	6.9	6.8	0.0
Entrees	6.8	7.1	7.3	6.0	3.4
Beverages	6.8	6.9	6.1	7.4	1.7
Bundled Meals	6.5	6.7	6.9	6.0	1.1
Appetizers	5.6	6.4	5.5	5.0	2.7
Snacks	5.6	5.3	6.1	5.5	2.0
Desserts	4.4	4.7	5.2	3.4	3.2

- Respondents rated "sides" as the most easily modified courses or meal parts that would help customers achieve or maintain a healthy weight.
- Respondents rated "desserts" as the least easily modified courses or meal parts that would help customers achieve or maintain a healthy weight.
- "Chefs" and "Managers" rated "entrees" and "appetizers" as a significantly more easily modified courses or meal part than the "other" group. ("Other" includes nutritionists and others.)

Area 3. What Are the Most Effective Ways to Promote Changes?

Table 7.

What are effective ways to promote menu items intended to help customers achieve or maintain a healthy weight?	All	Chef (n = 37)	Manager $(n = 62)$	Other (n = 12)	F
Other on-site materials (e.g., tray inserts, table tents, brochures,					
etc.)	7.0	7.0	7.1	7.0	0.0
Menus	7.0	7.4	7.1	6.3	1.9
Menu boards	6.9	7.0	7.4	6.4	1.7
Websites	6.1	6.2	5.7	6.3	0.8
Print Ads	5.8	5.9	5.8	5.9	0.0
TV/Radio Ads	5.2	5.3	4.8	5.4	0.6

- Respondents rated "other on-site materials" and "menus" as the most effective ways to promote menu items intended to help customers achieve or maintain a healthy weight.
- Respondents rated "TV/radio ads" as the least effective way to promote menu items intended to help customers achieve or maintain a healthy weight.
- There were no significant differences between comparison groups in ratings.

Area 4. What Are the Barriers to Introducing Healthy Items?

Table 8.

What are the barriers to offering a greater number of menu items that help customers achieve or maintain a healthy weight?	All	Chef (n = 37)	Manager (n = 62)	Other (n = 12)	F
Staff nutrition knowledge	7.1	6.4	6.9	7.9	2.6
Consumer preferences	7.0	6.9	6.6	7.4	0.9
Staff skill and training	6.5	5.8	6.1	7.6	2.6
Operational challenges	6.1	5.3	5.4	7.6	5.1
Ingredient pricing	6.0	5.9	5.9	6.3	0.1
Time	5.3	5.0	5.7	5.2	1.3
Ingredient availability	5.1	4.8	5.1	5.5	0.3

- Respondents rated "staff nutrition knowledge" as the most significant barrier to offering a greater number of menu items that help customers achieve or maintain a healthy weight.
- Respondents rated "ingredient availability" as the least significant barrier to offering a greater number of menu items that help customers achieve or maintain a healthy weight.
- "Chefs" and "managers" rated "operational challenges" as a less significant barrier than the "other" group. ("Other" includes nutritionists and others.)

Area 5. Which Factors Most Influence Body Weight?

Table 9.

In your opinion, which one of the following factors has an influence on body weight?	All	Chef (n = 37)	Manager $(n = 62)$	Other (n = 12)	F
Calories consumed	8.3	8.0	8.1	8.8	1.8
Total fat consumed	8.0	8.3	7.9	7.8	1.6
Carbohydrate consumed	7.0	7.1	7.2	6.7	0.5
Protein consumed	6.0	6.0	5.5	6.5	2.4
Water consumed	5.8	5.1	5.9	6.5	1.4
Fiber consumed	5.7	5.1	5.7	6.3	1.4

- Respondents rated "calories consumed" as the most significant influence on body weight.
- Respondents rated "fiber consumed" as the least significant influence on body weight.
- There were no significant differences between comparison groups in ratings.

Demographics

Age	Frequency	Percent
18-30	7	6.3
31-50	91	82.0
51 and over	13	11.7
Total	111	100.0

Gender	Frequency	Percent
Female	41	36.9
Male	70	63.1
Total	111	100.0

Years in the restaurant industry	Frequency	Percent
10 to 14	16	14.4
14-19	25	22.5
20+	63	56.8
5 to 9	6	5.4
Less than 5	1	.9
Total	111	100.0

Where are you located?	Frequency	Percent
Undetermined	3	2.7
Central	20	18.0
Northeast	36	32.4
Southeast	23	20.7
West	29	26.1
Total	111	100.0

How would you characterize your		
restaurant?	Frequency	Percent
Undetermined	1	.9
Buffet-style self- serve	2	1.8
Casual/Family restaurant	1	.9
Fine dining	4	3.6
On site/contract feeding Other	92	82.9
	9	8.1
Quick service/fast food	2	1.8
Total	111	100.0

Appendix H **Summary of National Polls Regarding Consumer Interest in Nutrition Information for Away-from-Home Foods**

Question	Poll	% Supportive/Agree	% Disagree
Restaurants should make	ARAMARK	83	
nutrition information	Corp., 2005 ²⁵²		
available for all menu items			
Support putting calorie info	Advertising Age,	72	
on menu boards at fast-food	2005^{253}		
restaurants			
Support requiring restaurants	Harvard Forums	62	
to list nutrition info—such as	on Health,		
calories—on menus	2003 ²⁵⁴		
Support requiring fast-food	Center for	67	23
restaurants to display the	Science in the		
calorie content of their foods	Public Interest,		
on menus and menu boards	2003^{255}		
Support a law requiring	Time/ABC,	61	
restaurants to list the calorie	2004^{256}		
count and fat content of all			
items on their menus			
Support requiring fast-food	California	87	12
and chain restaurants to post	Endowment ²⁵⁷		
nutritional information, such			
as caloric, fat, and sugar			
content, on their menus			

²⁵² C. Malone and J. Bland-Campbell (ARAMARK), New Insights on the Away-From-Home Eating Patterns and Nutritional Preferences of Americans, presentation at the North American Association for the Study of Obesity Annual Scientific Meeting, October 17, 2005. (Presenting results of an online nationwide survey of 5,279 adults.) See www.aramark.com/CaseStudyWhitePaperDetail.aspx?PostingID=420&ChannelID=221.

253 Lightspeed Research, national survey commissioned by *Advertising Age* and published March 21, 2005,

www.lightspeedresearch.com/pdffiles/9adage-mared-master.pdf, accessed March 18, 2006.

²⁵⁴ Lake, Snell, Perry & Associates, "Obesity as a Public Health Issue," a poll commissioned by the Harvard Forums on Health in 2003, with 1,002 respondents nationwide, www.phsi.harvard.edu/health reform/poll results.pdf, accessed March 18, 2006.

²⁵⁵ Global Strategy Group, "Menu Board Question," a poll commissioned by the Center for Science in the Public Interest in 2003 with a nationally representative sample of 600 respondents, http://cspinet.org/new/pdf/census menu board question.pdf, accessed March 18, 2006.

²⁵⁶ Time/ABC News poll, conducted May 10-16, 2004, with 1,202 respondents nationwide.

²⁵⁷ Field Research Corporation, "A Survey of Californians about the Problem of Childhood Obesity," a poll commissioned by the California Endowment in November 2003 with 1,068 respondents in California, www.calendow.org/reference/publications/ disparities in health.stm, accessed March 18, 2006.

Appendix I **Review of Selected Studies:** The Impact of Nutrition Information on **Menu Item Selection**

The standardized "Nutrition Facts" panel was one of the primary outcomes of the 1990 federal Nutrition Labeling and Education Act (NLEA). The panel, found on most packaged food products, lists information on the levels of calories, total fat, saturated fat, trans fat, sodium, other macronutrients, and key vitamins and minerals present in the food. While the NLEA covers packaged foods, food prepared for immediate consumption—such as restaurant meals, carryout foods, and foods served on airplanes or in cafeterias—was not included in these requirements.

Rising obesity rates have raised concern among many people in the public health, public policy, and medical fields. Consumers spent approximately 46% of their food budget in 2002 on awayfrom-home foods, ²⁵⁸ as compared to 26% in 1970. Food prepared outside the home tends to be higher in calories than foods eaten in the home; while away-from-home foods comprise 27% of the meals and snacks consumed by the average American, they provide 34% of the calories.²⁵⁹ The wide prevalence of overweight and obesity in the United States and the substantial number of calories obtained by Americans from away-from-home foods has given rise to the following question: "Does away-from-home food contribute to overweight and obesity in the U.S.?" And, if it might or does, "How might the provision of nutrition information regarding foods prepared away from home influence Americans' food choices? Would such information aid consumers in making lower-calorie or smaller-portioned food choices?"

A review of existing literature on this topic reveals that additional research is needed to better understand how consumers do or would react to, understand, and use nutrition information in the away-from-home foods setting. That said, that there may be important policy reasons to take action (e.g., right to know, do no harm, act now in the face of uncertainty due to the magnitude of the problem), even given the limited knowledge we have to date on these issues.

The literature review in this appendix contains three elements: (1) a review of studies that have examined the effects of nutrition information provision in away-from-home food settings; (2) a review of research that has examined the effects of claims and symbols on consumers' behaviors in these settings; and (3) a review of studies regarding unintended consequences and how to provide nutrition information.

²⁵⁸ J.N. Variyam, Nutrition Labeling in the Food-Away-From-Home Sector: An Economic Assessment, Economic Research Report #4 (Washington, DC: Economic Research Service (ERS), 2005).

The Keystone Forum on Away-From-Home Foods—Final Report

²⁵⁹ B. Lin, J. Guthrie, and E. Frazao, Away-From-Home Foods Increasingly Important to Quality of American Diet, Agriculture Information Bulletin #749 (Washington, DC: ERS, 1999.)

Summary of Findings: Influence of Nutrition Information Provision

The following studies assessed whether consumers could accurately estimate the caloric content of their food choices, and, when reliable nutrition information was provided, how it affected people's food choices.

Burton and Creyer (2004)²⁶⁰

This series of laboratory studies demonstrated that many consumers have very little knowledge of the high levels of calories, fat, and saturated fat found in many popular, less-healthful restaurant items. For example, for some items such chicken fajitas and chef salad, actual calorie levels were twice what consumers expected. When levels of calories, fat, and saturated fat substantially exceeded consumers' expectations, the provision of nutrition information had a significant negative effect on product attitude, purchase intention, and choice. The authors suggest that the provision of nutrition information on restaurant menus could potentially have a positive impact on public health by reducing the consumption of less-healthful menu items.

Burton, et al. (2006)²⁶¹

Burton and his colleagues explored how much the average consumer knows about the calories, fat, and other macronutrient levels found in foods served at restaurants. Their results show that consumers substantially underestimated the levels of calories, fat, saturated fat, and cholesterol found in many less-healthful menu items. When objective, quantitative nutrition information was provided, consumers had more unfavorable attitudes towards the less-healthful menu options. Consumers' purchase intentions for the less-healthful items were also significantly diminished by the provision of nutrition information.

Backstrand, et al. (1997)²⁶²

This study, conducted by the Center for Science in the Public Interest and New York University, found that even well-trained nutrition professionals could not accurately estimate the caloric content of typical restaurant meals. Although the dietitians were able to accurately estimate the caloric content of a cup of whole milk (the control in the study), they consistently underestimated the calories in restaurant foods and meals. Their estimations were off by large amounts—by 200 to 600 calories. For example, when shown a typical dinner-house hamburger and onion rings, the dietitians on average estimated that it had 865 calories, when it actually contained 1,550 calories. Since not even experts in the field of nutrition are able to accurately estimate the caloric content of restaurant foods, consumers are unlikely to do better.

Conklin, Cranage, and Lambert (2005)²⁶³

Conklin, Cranage, and Lambert examined the use of nutrition and ingredient information by college freshmen at the point of sale in campus dining facilities. Results showed that women

²⁶⁰ S. Burton and E.H. Creyer, "What Consumers Don't Know Can Hurt Them: Consumer Evaluations and Disease Risk Perceptions of Restaurant Menu Items," *Journal of Consumer Affairs* 38, no. 1 (2004): 121-145.

²⁶¹ S. Burton, et al., "Attacking the Obesity Epidemic: An Examination of the Potential Health Benefits of Nutrition Information Provision in Restaurants," *American Journal of Public Health*, forthcoming (2006).

²⁶² J. Backstrand, et al., Fat Chance (Washington, DC: Center for Science in the Public Interest, 1997).

²⁶³ M.T. Conklin, D.A. Cranage, and C.U. Lambert, "College Students' Use of Point of Selection Nutrition Information," *Topics in Clinical Nutrition* 20, no. 2 (2005): 97-108.

were more likely than men to use the nutrition information labels to make food choices. Whereas women used the nutrition information to identify and select lower-fat, lower-calorie foods, men used the information to select foods with higher levels of protein. These results confirm the findings of a previous research effort, which found that the provision of nutrition information can have a positive influence on the food purchase behaviors of college students.

Kral, Roe, and Rolls (2002)²⁶⁴

A study by Kral and her associates found that the provision of information about the energy density (i.e., calories per ounce) of foods did not have an effect on the weight of food consumed. The daily intake of calories was directly related to energy density, regardless of whether or not nutrition information was presented. Interestingly, however, the relationship between dietary restraint (that is, whether or not the consumer was consciously trying to regulate food consumption for the purpose body weight regulation) and food intake differed depending on whether or not nutrition information was presented. While the intake of food by restrained eaters was not influenced by information provision, unrestrained eaters consumed less food when nutrition information was presented.

Kozup, Creyer, and Burton (2003)²⁶⁵

Kozup, Creyer, and Burton found that when favorable nutrition information was presented on restaurant menus, consumers had more favorable attitudes towards the items and had higher purchase intentions. When unfavorable nutrition information was presented, there was a negative influence on product attitudes and purchase intentions. The authors note that the results imply that if restaurants were required to disclose nutrition information, consumers would be more likely to choose more healthful menu items. In addition, requiring restaurants to provide nutrition information may encourage the healthfulness of their menu options.

Milich, Anderson, and Mills (1976)²⁶⁶

In a study in a cafeteria setting, signs indicating the calorie content of available foods significantly decreased the number of calories that people purchased.

Summary of Findings: Influence of Claims and Symbols

The following studies sought to understand how consumers react to more generalized nutrition information than the numeric provision of calories, through such means as claims, "health" symbols, or other communication devices. One general worry of many is that consumers will actually avoid selections labeled "healthful" or "low fat" for fear (or experience) of poor flavor and taste.

²⁶⁴ T.V. Kral, L.S. Roe, and B.J. Rolls, "Does Nutrition Information about the Energy Density of Meals Affect Food Intake in Normal-Weight Women?" *Appetite* 39, no. 2 (2002): 137-45.

The Keystone Forum on Away-From-Home Foods—Final Report

²⁶⁵ K.C. Kozup, E.H. Creyer, and S. Burton, "Making Healthful Food Choices: The Influence of Health Claims and Nutrition Information on Consumers' Evaluations of Packaged Food Products and Restaurant Menu Items," *Journal of Marketing* 67 (2003): 19-34.

²⁶⁶ R. Milich, J. Anderson, and M. Mills, "Effects of Visual Presentation of Caloric Values on Food Buying by Normal and Obese Persons," *Perceptual and Motor Skills* 42 (1976): 155-162.

Albright, Flora, and Fortmann (1990)²⁶⁷

Albright et al. explored the sales of food "labeled" as low fat/low cholesterol in four family-style restaurants. Two of the four restaurants showed an increase in sales. In general, women and older patrons were more responsive to the menu claims. It is unclear why only two of the four stores showed increased sales.

Anderson and Haas (1990)²⁶⁸

In this study, heart symbols were placed on "heart-healthy" menu items in 167 restaurants. Of the 56 items that were eligible for the symbol, sales increased for 52 of them, while 4 remained the same and 2 decreased.

Colby, et al. (1987)²⁶⁹

A study by Colby, et al., attempted to influence consumers to make more-healthful selections in a family-style restaurant. They described a menu item in one of three different ways. In one case the message stressed that the selection was healthful because it was relatively low in fat, sodium, and cholesterol. A second message stressed the flavor of the food, while also noting that the selection was healthful. In the third case, the menu item was simply identified as a daily special. Their result showed that patrons were more likely to choose the more healthful item when the message emphasized flavor. This suggests that emphasizing the good taste or flavor of a menu item, in addition to presenting information about its healthfulness, may be an important component of any food labeling program.

Fitzpatrick, Chapman, and Barr (1997)²⁷⁰

Consumer satisfaction with the "Fresh Choice" restaurant-based nutrition program was assessed in a study by Fitzpatrick and her colleagues. The purpose of the Fresh Choice program was to increase the availability and accessibility of good-tasting, lower-fat menu items. The research found that consumers were significantly more satisfied with the lower-fat items than with the regular menu items. The authors concluded that consumers will support restaurants that provide lower-fat choices on the menus.

Sproul, Canter, and Schmidt (2003)²⁷¹

Sproul, Canter, and Schmidt examined how labeling lunch selections as "healthy" influenced sales. The study, conducted in an Army cafeteria, revealed no significant differences between the sales of the labeled "healthy entrées" and the unlabeled same entrées. This finding may suggest that, in this case, individuals who were interested in making more healthful food selections were able to do so without the additional labeling information, or, the provision of nutrition information did not seem to motivate individuals to make more-healthful selections.

²⁶⁷ C.L. Albright, J.A. Flora, and S.P. Fortmann, "Restaurant Menu Labeling: Impact of Nutrition Information on Entree Sales and Patron Attitudes," *Health Education Quarterly* 17 (1990): 157-167.

²⁶⁸ J. Anderson and M.H. Haas, "Impact of a Nutrition Education Program on Food Sales in Restaurants," *Journal of Nutrition Education* 22 (1990): 232-238.

²⁶⁹ J.J. Colby, et al., "Promoting the Selection of Healthy Food through Menu Item Description in a Family-Style Restaurant," *American Journal of Preventative Medicine* 3 (1987): 171-177.

²⁷⁰ M.P. Fitzpatrick, G.E. Chapman, and S.I. Barr, "Lower-Fat Menu Items in Restaurants Satisfy Customers," *Journal of the American Dietetic Association* 97 (1997): 510-14.

A.D. Sproul, D.O. Canter, and J.B. Schmidt, "Does Point-of-Purchase Nutrition Labeling Influence Meal Selections: A Test in an Army Cafeteria," *Military Medicine* 168, no. 7 (2003): 556-560.

Stubenitsky, et al. (1999)²⁷²

Stubenitsky, et al., examined the influences of nutritional information on meal quality expectations, food selection, and macronutrient intake. In the training restaurant of a hotel school, patrons were assigned to one of four treatment conditions. In the full-fat blind condition, no information was presented about the target item, smoked haddock with Welsh rabbit. In the reduced-fat blind condition, no nutrition information was presented but the entrée was prepared using lower-fat ingredients. In the reduced-fat informed and reduced-fat informed with details conditions (that is, patrons were told that the entrée was prepared with reduced-fat cheese and skim milk), the target item was specifically identified as a lower-fat option.

The results show that the proportion of patrons selecting the target item was not significantly higher when no information was provided versus when the entrée was identified as lower in fat. The use of the claim "low fat" had no influence on product acceptance or ratings of sensory quality. However, the authors note that provision of a lower-fat, lower-energy entrée did have a direct effect on fat and energy intake. That is, patrons who chose the lower-fat entrée consumed less fat and fewer calories overall, since they did not compensate for their more healthful selection by consuming more of the other meal components (e.g., dessert). The authors note that the results of both this study and prior research ²⁷³ suggest that provision of a lower-fat, lower-energy main entrée identified as such is an approach that would provide dietary benefits and have good consumer acceptance.

Johnson, et al. (1990)²⁷⁴

This study considered behavior in a cafeteria restaurant setting. "Lower-calorie selection" signs appeared within the entree, salad, and vegetable categories. The labeling had little effect on food purchases. Restrained eaters and women were found to underestimate total calories to a greater extent.

Summary of Findings: Unintended Consequences and How to Provide Information

Though there is little information in the literature on this issue, some stakeholders are concerned about the potential unintended consequences of providing nutrition information. For instance, consumers may choose a diet soda because it has no calories, but then order a high-calorie ice cream sundae because they "earned it." Several studies have found that consumers, when informed that they consumed a low-fat product, subsequently consumed more energy during the day than consumers who were informed that they consumed a high-fat product. That is, some

²⁷² K. Stubenitsky, et al., "Effect of Information and Extended Use on the Acceptance of Reduced-Fat Products," *Food Quality and Preference* 10 (1999): 367-376.

²⁷³ K. Stubenitsky, et al., "The Influence of Nutritional and Sensory Descriptive Information on Measures of Food Selection and Acceptance in a Restaurant," *Appetite* 29 (1997): 265.

W.G. Johnson, et al., "Dietary Restraint and Eating Behaviors in the Natural Environment," *Addictive Behavior* 15 (1990): 285-290.

²⁷⁵ D.J. Shide and B.J. Rolls, "Information about the Fat Content of Preloads Influences Energy Intake in Healthy Women," *Journal of the American Dietetic Association* 95 (1995): 993–998; and F.A. Caputo and R.D. Mattes,

consumers behave as if they have a "nutrient budget" and use the available nutrition information to adjust their overall, daily macronutrient intake.²⁷⁶ Other participants are concerned that a focus on just calories may unintentionally skew consumer decisions away from nutrient-dense foods to lower-calorie and less-nutrient-dense foods and beverages.

There are no publicly available studies that compare and contrast different methods of providing nutrition information in terms of format or means, such as via menu board, table tent, website, and so forth. Focus group research from the Food and Drug Administration does suggest that, when asked, many consumers prefer more nutrition information, specifically calories, particularly on menu boards, and believe it would assist them in selecting "healthier food choices if and when they wanted to eat healthier." However, how consumers would actually act and react when provided such information in a restaurant or more controlled setting is not known.

"Human Dietary Responses to Perceived Manipulation of Fat Content in a Midday Meal," *International Journal of Obesity* 17 (1993): 241-244.

²⁷⁶ Variyam, Nutrition Labeling in the Food-Away-From-Home Sector, 2005.

²⁷⁷ ORC Macro, Restaurant and Food Labeling Focus Group Research: Summary Report (Rockville, MD: FDA, 2003).

Appendix J Approaches to Providing Nutrition Information

This appendix evaluates a number of means, currently being used by foodservice companies, to provide information to consumers. The "pros" and "cons" described for each were developed jointly by individuals with a variety of perspectives (e.g., from industry, academia, consumer organizations, voluntary health organizations, and others). The analysis considers information as provided about a given outlet's menu items, and so does not consider how consumers might use nutrition information to choose foodservice venues themselves. Finally, it is important to remember that a consumer may encounter multiple sources of information in one visit to an outlet (e.g., on a printed napkin, a brochure, and poster).

Websites

Pros:

- Can include detailed information and a wide range of nutrients
- Can compare options side by side
- Almost half of large chains already have nutrition information on the web, suggesting that this is a practical mode for at least much of industry
- Can have menu calculators and interactive programming to provide people with information for special orders and whole meals, without having them do the math themselves
- Some websites can calculate entire meals—adding up nutrition information, making substitutions, and allowing the consumer to determine whole-meal nutrition, not just item by item
- Can be graphically very interesting and innovative, thus drawing in audiences, especially younger ones

- The information is not at the point of purchase/decision-making—it has to be accessed before or after going to a restaurant
- Customers can only take advantage of it when the decision to eat out (and perhaps the decision of where to eat) is already made
- Since use of a website requires an extra, advanced measure for consumers, it is helpful only to people who are interested in and motivated to consider the information
- Price and nutrition information are not in the same place, therefore consumers cannot make tradeoffs between nutrition and cost
- The customer has to have access to a computer and an internet connection
- For much of the industry (small restaurants, etc.), technology is expensive
- Because websites organize information differently, information can be hard to find and use easily in the absence of standardization

- Some websites can calculate entire meals but make it difficult to make side-by-side comparisons of different menu choices
- The format can be hard to read on the screen or even when printed out
 - Often there is information for so many nutrients that it can be hard to read and make comparisons

Servers Verbally Offering and, If Requested, Providing Written Information at the Point of Sale/Decision (with Aid from Electronic Registers, Printed Sources, or Handheld Devices)

Pros:

- Information is at the point of purchase and decision-making
- Has the potential to be interactive, depending on the training of staff (i.e., consumers could ask questions and interact)
- The delivery of the information is more "human" and personal than other modes

Cons:

- May slow the food ordering process and affect customer service time
- Requires more staff training, which can be costly, difficult with high labor turnover, and variable in how the information is communicated to the customer
- Hard to compare options because the customer won't see options side-by-side
- Hard for the server to communicate a lot of numbers quickly
- Difficult for the customer to understand a lot of numbers without seeing them in print
- Price and nutrition information may not be in the same place
- There may be a stigma associated with asking for assistance or information related to overweight and obesity
- Places nutrition information and making informed choices outside the norm—sets it apart in a
 way that may make healthier eating and informed choices seem like an exception rather than
 the norm

Menus and Menu Boards (for Standard Menu Items)

There are some differences between the attributes of menus and menu boards, but many pros and cons are similar, and most restaurants have one or the other.

Pros:

- Easy to find and linked to an essential information method in the business
- At the point of purchase and decision-making
- Can use and compare options at the point of purchase
- Is what state legislatures and Congress are considering requiring
- Would provide restaurants with an incentive for reformulation
- Allows people to consider price and nutrition information together in the same place

Cons:

- Can't provide the full range of nutrients on the menu because of lack of space (but could be supplemented with more information in writing, upon request)
- Consumers may not be able to add up individual items to construct a full meal choice and determine its nutritional value
- Consumers may be making decisions on isolated nutrition information rather than tradeoffs across multiple nutrition factors (for instance, just making choices based on calories without regard for sodium, carbohydrates, kinds of fat, and other considerations that may be important to individuals' needs)
- Only provides information for standard menu items, and so does not allow people to determine how the nutrition information changes for special orders
- May slow ordering (on menu boards more than menus)
- Some consumers may be put off or not want to know
- Presents uncertainty/risk for foodservice in terms of affecting choices within a restaurant (ordering lower-profit items, reducing quantities consumed) as well as across restaurants and other sources of meals (substitution effects across other restaurants, other away-from-home food outlets, or eating at home)
- Concern within industry that providing information in this way may act as a disincentive for customers to purchase "healthier" items (i.e., because of the possible stigma about compromised taste and flavor associated with "healthy" or health-oriented foods)

"Second" Menu with Nutrition Information—Provided upon Request

Pros:

- Should be easy to read, use, and compare options
- Allows people to consider price and nutrition information together in the same place
- Isolates the intervention to seekers who are most likely to change their behavior
- Does not offend or turn off customers who do not want the information

Cons:

- Customers might not know it is available or know to ask for it (although servers could routinely offer it)
- Can get lost: employees may not be able to find the alternative menus, or it might take them too long to track them down
- Puts extra burden on people who want to make informed choices; they are the exception rather than the norm (i.e., does not make the healthier choice the easy choice)
- Embarrassing or uncomfortable to ask for—there may be a social stigma associated with asking for a menu because one is on a diet, has a disease, etc.

Nutrition Information on a "Health-Oriented" Section of the Menu

Pros:

• Is at the point of decision/purchase

- Allows people to consider price and nutrition information together in the same place
- Focuses on interested seekers who are most likely to change their behavior, and may not confuse them with too much information

Cons:

- Information is for a limited number of menu items (usually a small percentage of the menu)
- Can't compare nutrition information for health-oriented items to other menu items and determine what the tradeoffs are
- Places health-oriented choices outside of the normal menu—sets it apart in a way that may make healthier eating seem like an exception rather than the norm
- Many people have had negative past experiences with bad-tasting health-oriented foods and may assume that the health-oriented menu items don't taste as good

Health-Related Symbols for Menu Items

Pros:

- Is at the point of purchase/decision
- May help people to identify healthier food choices
- Can target audiences for various purposes, such as seeking to aid those with heart disease
- May help those with low health literacy: easy to use and understand and does not require the customer to do math, read a lot, or weigh multiple factors quickly
- Customers don't have to do the math—simple, targeted, and easier to understand than numbers

- Criteria for "healthy" can vary among different restaurants, can be confusing to customers, and can be suspect or misleading (e.g., an item denoted as low in carbohydrates might be high in fat or calories)
- Can't compare nutrition information for health-oriented items to other menu items and determine what the tradeoffs are
- Places health-oriented food outside of the normal menu—sets it apart in a way that positions healthier eating as an exception rather than the norm
- Many people have had negative past experiences with bad-tasting health-oriented foods and may assume that the health-oriented menu items don't taste as good
- Symbols don't provide detailed, clear information. "Health" may be subject to arbitrary standards and food fads, or left undefined. May not be providing new information (if, say, the products is generally known to be lower in calories). May be based on a controversial or suspect standard (e.g., low-carb chicken wings).

Table Mats, Table Tents, or Other Displays at the Table (Distinct from Point of Sale)

Pros:

- Information may be at the point of purchase and decision-making (if at a sit-down restaurant)
- Detailed information can be provided for a wide range of nutrients
- For repeat customers, might affect choice at next purchase

Cons:

- Price and nutrition information are not in the same place
- Not at the point of purchase
- May not be noticed by customers
- Easy to lose, disappear, and not be available (especially in quick-service restaurants where individual operatives' practices may vary even with company standards)
- Places nutrition information and making informed choices outside of the normal menu—sets
 it apart in a way that may make healthier eating and informed choices seem like an exception
 rather than the norm
- May add clutter to the table and detract from the dining experience, depending on the atmosphere

Tray Liners, Cups, Napkins or Other Packages, Containers, Receipts (After Order but Linked Closely to Food Item(s))

Pros:

- Can provide more detailed information on a tray liner or directly on a container than on a menu board or probably a menu
- If more than one person is eating, consumers might make a post-purchase comparison with one another's choices that leads to a different selection on the next order, especially for repeat consumers
- Could provide nutrition information in a standard Nutrition Facts label format and thus be consistent with nutrition information provided for grocery goods

- Price and nutrition information are not in the same place
- People obtain the information after they have already ordered
- If containers are used for multiple items (e.g., different kinds of sandwiches), information would need to provided for each of those items, possibly causing space constraints on the packaging surface
- Tray liners are under the food and thus the nutrition information may not be easily visible (i.e., one has to take the items off the liner to read it)
- Tray liners may be quickly stained, ignored, and thrown away, since they rest underneath food
- If information is on the item's packaging, it makes it difficult to make comparisons among items, unless fellow diners are present to enable comparisons among different items

Electronic Kiosks

Pros:

- Can provide detailed nutrition information on a range of nutrients
- Can have menu calculators and interactive programming to provide people with information for customized orders and whole meals, without having to do the math themselves
- Are less obtrusive and may be more acceptable overall to customers (more discreet)
- Can target those with the interest
- Can be graphically interesting and innovative, thus drawing in audiences, especially younger ones
- Can be at or near the point of decision

Cons:

- Price and nutrition information are not in the same place
- Customers might not know that the kiosk is available
- Requires consumers to take special effort to access the information, rather than having it proactively provided to all consumers
- A limited number of people can use a kiosk at any one time
- People not familiar with it may take time to learn to use it
- Maybe too time-consuming to use
- The equipment is costly, raising a question of who should pay for it (e.g., chains, franchisees, client organizations)

Reference Books, Posters, Handouts, Brochures, etc.

Pros:

- Can include detailed information on a wide range of nutrients
- Can compare options side-by-side across the full range of choices
- Many large fast-food chains already have these formats, so it is practical for the restaurant

- Can be hard to find if the information is in varying locations within the same restaurant or at different outlets of the same chain or between different chains
- Consistent availability is uncertain (they get lost, employees can't find them, they run out and are not replenished)
- Can take too much time to find the information
- Can be hard to use; large complicated tables listing too many nutrients can be overwhelming
- May use small fonts that can be hard to read
- Price and nutrition information are not in the same place
- People don't want to lose their place in line to track down the information
- Depending on how prominently they are provided, can require extra effort from consumers who want to make informed choices

Appendix K Key Abbreviations

AOAC Formerly known as the Association of Official Analytical Chemistry

ATUS American Time Use Survey

BMI body mass index

CARU Children's Advertising Review Unit

CDC Centers for Disease Control and Prevention (HHS)
CSFII Continuing Survey of Food Intakes by Individuals

DGA Dietary Guidelines for Americans
ERS Economic Research Service (USDA)
FDA Food and Drug Administration (HHS)

HDS Health and Diet Survey

HHS U.S. Department of Health and Human Services

NBER National Bureau of Economic Research NCHS National Center for Health Statistics (CDC)

NHANES National Health and Nutrition Examination Survey

NLEA Nutrition Labeling and Education Act

USDA U.S. Department of Agriculture

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

NEW YORK STATE RESTAURANT ASSOCIATION,

No. 08 Civ 1000 (RJH)

Plaintiff,

-against-

NEW YORK CITY BOARD OF HEALTH, NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE, and Thomas R. Frieden, In His Official Capacity as Commissioner Of the New York City Department of Health And Mental Hygiene, DECLARATION OF MARY T. BASSETT

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De	I CH U	144.11	13.

MARY T. BASSETT, M.D. M.P.H., hereby declares under penalty of perjury:

- 1. I am Deputy Commissioner of the Department of Health and Mental Hygiene (the" Department") of the City of New York responsible for the Division of Health Promotion and Disease Prevention. I have held this position since 2002. I earned my medical degree from Columbia University's College of Physicians and Surgeons, and my master's degree in public health from the University of Washington where I was a Robert Wood Johnson Clinical Scholar. I am also an Associate Professor of Clinical Public Health in the Division of Epidemiology at the Mailman School of Public Health, Columbia University and an Associate Editor for the American Journal of Public Health. I have over 20 years' experience in public health, including both policy development and research. I have authored or co-authored more than 70 articles in peer-reviewed medical and scientific journals.
- The Department enacted Regulation §81.50 as part of its response to the obesity epidemic in New York City. The purpose of §81.50 is to inform patrons of chain

restaurants of the calorie content of food options at the time and location at which consumers make their food purchase decisions. Currently, consumers are not aware of the calorie content of menu options, and without this information they cannot make decisions about food purchases that could help them avoid unhealthy weight gain.

- 3. In 2007, the Department conducted a survey of fast food chains that would be covered by the previously enacted §81.50 to gather information about the availability of calorie information reported by patrons of these chains and the calorie content of their purchases.
- 4. I and my co-authors have prepared a manuscript for publication which summarizes the methods and results of this survey. This manuscript is currently under review by a peer-reviewed journal.
- 5. The submission manuscript, which will likely be modified before publication, is submitted as Exhibit A. It is entitled Purchasing Behavior and Calorie Information at Fast-Food Chains New York City, 2007, and the authors, all of the Department, are Mary T. Bassett, Tamara Dumanovsky, Christina Huang, Lynn D. Silver, Candace Young, Cathy Nonas, Thomas D. Matte, Sekai Chideya, and Thomas R. Frieden.
- 6. I refer to the declaration by David B. Allison, which plaintiff submitted in support of its motion. Dr. Allison offers a description of his academic accomplishments in his declaration. A listing of his industry associations, provided as part of the declaration of potential conflict of interest for a peer-reviewed journal, is provided in Exhibit B.
- 7. Dr. Allison discusses at length the Department's survey of patrons of restaurants in New York City, and cites what he perceives as numerous "limitations" and "flaws."

 The "limitations" and "flaws" he lists essentially point out that the study was not a

randomized controlled trial of the effect of providing calorie information on long-term obesity rates in New York City. However, the Department never claimed that this study was of this type, nor does the study need to be of this type to be useful and informative. While randomized controlled trials are often considered the strongest form of scientific evidence, many other study designs are widely used and accepted in the scientific literature. Indeed, none of the studies that Dr. Allison cites in considering whether there might be deleterious effects of providing calorie information are randomized controlled trials of the effect on an intervention on obesity rates.

- 8. Dr. Allison's statement that the actual Department study records show that only a few Subway sites had decals is based on analyses performed without direct contact with the study staff, using FOIL-requested logs, and it reflects an incomplete understanding of the field research methods. The primary use of the calorie question on the observation log was to exclude sites that were ineligible because they had on their own already provided calorie information on menu boards. The data collectors' priority was not to assess the other ways in which calorie information was available. Although they were not required to provide it, research staff nonetheless made notation of calorie information at 75% of surveyed Subway sites, and for 49% of those sites they went further to specifically note that such information was placed on glass case decals. At the time of this survey, Subway provided its New York City outlets with such display case decals that provided calorie information on certain items.
- 9. Dr. Allison suggests that fast food consumption is more common among the poor, and also notes that the poor are at higher risk of obesity than the non-poor. As a result, he argues, the relationship between fast-food and obesity is "confounded" by the

relationship between fast food and poverty, as poverty is associated with both fast-food and obesity. Dr. Allison makes much of the problem of "confounding", arguing that overweight people go to fast food restaurants because they are poor and poor people are overweight for a host of reasons. As a consequence, he suggests, it is being poor, not the fast food, that made people overweight. This is speculative. But from a public health perspective, if indeed fast food chains cater to those at independent risk of being obese regardless of reason, it is especially appropriate that patrons in these settings be assured access to calorie information. By Dr. Allison's logic, if the confounding by poverty is a reason to refrain from providing calorie information at fast-food restaurants, we would also not target senior centers for influenza vaccination because the senior center is not the cause of being old and at risk for fatal influenza.

- 10. The Department study was designed first to determine the proportion of consumers who see and use calorie information, and second to estimate the caloric content of their purchases in a representative sample of establishments that would have been required to provide calorie information under the previous §81.50. The unit of randomization was the covered establishment; this "cluster" randomization approach is widely used in scientific studies. Inferential statistics were performed and demonstrated that the differences in seeing information between restaurant types, and in the calorie content of purchases between Subway patrons who saw and those who did not see information, were statistically significant (p< 0.05).
- 11. This study provides three pieces of evidence to add to the existing scientific literature on use of calorie information:

- Customers of restaurants that displayed calorie information at the point of purchase were far more likely to see this information than customers of restaurants that provided the information on napkins, tray liners, and websites;
- A substantial percentage of customers who saw calorie information reported that it affected their purchase – a measure of the degree to which they appreciate and value the information; and
- Customers who saw calorie information purchased significantly fewer calories than those who did not.

These pieces of evidence are consistent with the many other studies cited in the Notice of Intent for §81.50 and further show that it is reasonable to believe that routine provision of calorie information might contribute to reducing obesity levels or slowing the obesity epidemic in NYC.

12. Dr. Allison is critical of the methods the Department used to estimate the potential health benefits of providing calorie information (p. 26-28). The Department is neither required nor obliged to estimate the number of cases of obesity that might be prevented by §81.50, but it nonetheless did so to help the Board of Health in its consideration of the rule. Any estimate of this nature requires certain assumptions and projections, which is why it is called an estimate. Dr. Allison claims that: 1) the estimate of calorie reduction per meal is invalid, 2) any per-meal calorie reduction would likely not affect all persons equally, and 3) the slope of the relationship between caloric intake and weight gain in an individual changes as that individual's body mass increases.

My responses to the above-mentioned point raised by Dr. Allison are as follows:

Filed 02/15/2008

- The per-meal calorie reduction used to produce the estimate was 50 calories. This is based on the 48-calorie difference between Subway patrons who saw and Subway patrons who did not see the calorie information. It is a minimal estimate that can be drawn from the study and is far lower than the 92-calorie difference between patrons who said the information affected their purchase and those who said it did not. Furthermore, the Department makes it clear in its statement that its estimates are contingent upon this assumption: "if the reduction in calories in covered FSEs were similar to what occurred at Subway, over the next five years at least 150,000 fewer New Yorkers..."
- It is true that per-meal calorie reductions are unlikely to affect all persons equally. However, whether the reductions would be greater in persons who are thin or overweight is unknown. Since overweight persons are more likely to want to lose weight than thin persons, §81.50 may have a larger impact on the purchases of people who are overweight and most likely to benefit from it. Nonetheless, in the face of this uncertainty, the Department estimate assumes an equal calorie reduction across all customers of covered restaurants, which is a conservative assumption. The uncertainty associated with this assumption could either decrease or increase the estimate of the number of persons who would benefit.
- The Department is fully aware of the effect that Dr. Allison discusses between body mass and weight gain (p. 29). However, this effect is not large for weight gains of a few pounds (see Dr. Allison's graph), which would be the approximate average population weight gain over five years estimated by the

Department. Furthermore and most important, because of the inherent uncertainty of the assumptions and methods, including this effect, the Department reduced its point estimate of 197,000 and worded it as "at least 150,000." Even if the number were somewhat lower than this conservative estimate, the estimate's value is to show that what may appear as a small change in calorie consumption in chain restaurant meals has the potential to benefit the health of a large number of New Yorkers.

I declare under penalty of perjury pursuant to 28 U.S.C. §1746 that the foregoing is true and correct.

Executed on February 8, 2007

Mary T. Bassett, M.D., M.P.H.

Purchasing Behavior and Calorie Information at Fast-Food Chains – New York City, 2007

Key words: Fast-food, energy intake, nutritional information, calorie labeling

Text word count: 1,515

Objectives: Fast-food restaurants are not required to provide calorie information, and only one fast-food chain in New York City (Subway) provides calorie information at point of purchase. We sought to characterize fast-food patrons' purchases and their observation and use of calorie information.

Methods: We conducted a cross-sectional survey of adult patrons of randomly sampled locations of 11 fast-food chains with publicly available nutrition information in New York City.

Results: We collected purchase receipts from 7,318 patrons. Patrons purchased a mean of 827 calories, with 33.5% purchasing ≥1,000 calories. Subway patrons were more likely to report seeing calorie information than other chains' patrons (31.5% vs. 4.3%, p<0.001). Subway patrons who reported seeing calorie information purchased 51.7 fewer calories than those who did not. Patrons who reported seeing and using calorie information purchased 98.9 fewer calories than those who saw, but reported not using this information.

Conclusion: Fast-food restaurant patrons purchase large quantities of calories per meal, and very few patrons report seeing calorie information. Placement of calorie information at point of purchase is associated with lower calorie purchases among patrons reporting seeing information.

INTRODUCTION

Rates of obesity and its health complications are increasing rapidly in the United States. Fast-food is typically calorie-dense and has been associated with increased calorie intake, weight gain, overweight, and obesity. 1-5 Despite this, fast-food restaurants are not required to provide nutritional information, and only one large fast-food restaurant chain in New York City (Subway) currently lists calorie information at the point of purchase. Various state and local governments, including New York City's, are considering requiring restaurants to post calorie information prominently. The New York City Department of Health and Mental Hygiene (DOHMH) conducted a large cross-sectional survey to characterize patrons' fast-food purchases and their observation and use of calorie information.

METHODS

Sampling Strategy

A roster of all licensed food service establishments is maintained by DOHMH. Licensed food service establishments that, as of March 1, 2007, provided calorie information publicly (either posted on site or on the internet) were eligible for inclusion in the study. Eleven food service establishment chains* accounted for nearly 90% of eligible non-coffee, non-snack fast-food establishments; the sampling frame was limited to 1,064 sites, of which 185 (17.4% of all eligible) were sampled.

Data Collection

^{*} Chains included: Au Bon Pain, Burger King, Domino's, Kentucky Fried Chicken (KFC), McDonald's, Papa Johns, Pizza Hut, Popeye's, Subway, Taco Bell and Wendy's. Ice cream chains were excluded from the food service establishment sample.

Data were collected from noon to 2:00 pm on weekdays from March 27 through June 8, 2007. Patrons entering sites were approached. Those who agreed to participate were asked, upon exiting, to answer a brief survey and turn in their receipts in exchange for a \$2 NYC Metrocard (valid for one subway or bus ride). Adult patrons (age ≥18 years) who agreed to participate were asked: (1) "Was this purchase just for you?" (2) "Can you tell me what you ordered today?" (3) "What extras, modifications or condiments did you add?" (e.g., dressing, mayonnaise, toppings; "diet" or "regular" beverage) (4) "Did you see calorie information in the restaurant?" and, if yes, (5) "Did the information affect your purchase?" The survey was conducted in English; personal identifiers were not collected. All items listed on receipts were entered into a database.

Data Analysis

Calories were ascribed to each item using chains' website-published calorie information as of March 1, 2007, and adjusted based on patrons' reports of extras or customizations for which calorie information was also available. Patrons not identifying the specific type or quantity of extra were assigned that category's lowest caloric value (e.g., a patron did not specify the type of salad dressing selected, therefore one serving of "vinaigrette" dressing was assigned because it had the fewest calories of all dressing options). SPSS 15.0 Complex Samples module (SPSS Inc., Illinois) was used for all statistical analyses. Two-tailed t-tests, alpha <0.05, were used to test for differences in mean calories.

RESULTS

Eighteen (9.7%) of the 185 sampled sites were excluded: seven were located in non-public spaces (e.g., airport, mall); eight were closed; two shared names, but not affiliations, with sampled chains; one had non-cooperative management; and one yielded no valid receipts. From the remaining 167 sites, 7,750 receipts and surveys were collected, of which 432 (5.6%) were

excluded because the purchase was for someone other than the patron, the receipt was from a non-sampled fast-food chain, or the receipt listed ≥1 item with an undetermined caloric value. Because of logistical challenges, restaurant outlets with a high volume (>150 patrons during the survey period) of customer traffic had lower rates of survey participation (33.3%) than did lower-volume sites (60.2%); overall participation was 55.2%.

Patrons purchased a mean of 827.4 calories, with 33% purchasing \geq 1,000 calories, and 15% purchasing \geq 1,250 calories (Table). Chicken chain patrons purchased the most calories and sandwich chain patrons purchased the fewest calories.

Reported Observation of Calorie Information

Ninety-eight percent (7,152/7,318) of respondents answered the survey question assessing observation of calorie information. Excluding Subway patrons, only 4.3% of patrons reported seeing calorie information as currently provided. Subway patrons were much more likely to report seeing calorie information than patrons of other chains (31.5% vs. 4.3%, p<0.001).

Among Subway patrons, those who reported seeing calorie information purchased 51.7 fewer calories than those reporting not seeing calorie information (713.8 calories vs. 765.5 calories, p=0.006), and fewer purchased meals with \geq 1,000 calories (17.4% vs. 23%, p=0.007) and \geq 1,250 calories (7.4% vs. 10.3%, p<0.03). Of Subway patrons who reported seeing calorie information, 37% reported that this information had an effect on their purchases. Those who reported seeing and using calorie information purchased 98.9 fewer calories than those who reported seeing the information and that it had no effect (646.9 calories vs. 745.8 calories, p<0.001). Such patrons

were also less likely to purchase ≥1,250 calories (p<0.03, Table). There was no difference in mean calories purchased by patrons reporting seeing but not using calorie information and patrons who reported not seeing calorie information (745.8 calories vs. 765.5 calories, p=0.3).

DISCUSSION

Despite its public availability, >95% of food service establishment patrons (excluding Subway patrons) reported not seeing calorie information. This finding is consistent with previous studies. ^{6,7} In comparison, Subway's placement of limited calorie information on deli cases near the registers, though not prominent, was associated with a much higher proportion of patrons seeing calorie information. Furthermore, more than one third of Subway patrons reported that this information affected their purchase. Objective measurement of calorie content through examination of receipts confirmed that patrons who reported seeing and using calorie information purchased fewer calories than those reporting they did not see and/or use calorie information.

The importance of providing calorie information is supported by the finding that patrons purchased foods with high energy contents: one-third of patrons purchased more than 1,000 calories for a single meal. Caloric intake is rising in the U.S. in parallel with the obesity epidemic: between 1971 and 2000, Americans' average daily caloric intake increased approximately 200-300 calories.^{1, 8, 9} Fast-food, which represents approximately 74% of all restaurant traffic nationally (marketing research data, The NPD Group/CREST), typically contains more calories per serving than food prepared at home.^{1, 2, 4}

New York City and several other jurisdictions have considered requiring certain restaurants to post calorie information on their menus and menu boards. At the time of this study, Subway already displayed calorie information for selected items at the point of purchase somewhat visibly. Despite this display, only one in three Subway patrons reported seeing calorie information, making it unlikely that less prominent formats – such as charts on counter mats, distant walls or posters, or on a website – would be seen by many patrons. Even more prominent displays, such as information provided on menu boards, could be expected to increase the proportion of patrons seeing – and using – calorie information.

The findings of this report regarding the association of caloric content of purchases with observation of calorie information are subject to at least three limitations. First, Subway patrons might not be representative of all chain restaurant patrons: Subway patrons purchased fewer calories than other chains' patrons. This could indicate that food available at Subway was lower in calories or that Subway patrons were more likely to purchase food with fewer calories than other chains' patrons. However, even when the analysis was restricted solely to Subway patrons, those seeing calorie information purchased fewer calories. Furthermore, Subway is the largest non-coffee fast-food chain in New York City, and its popularity suggests broad appeal; it is likely that many patrons of other chains would also be interested in and use calorie information if it were prominently displayed. Second, it is possible that Subway patrons who reported seeing calorie information did so because they were more concerned about weight than Subway patrons who reported not seeing calorie information. However, patrons who reported seeing but not using calorie information and patrons who reported not seeing calorie information purchased similar calories, indicating comparable purchasing patterns. Third, study respondents may have

differed from patrons choosing not to participate. However, data were collected over the busy lunch period, and the proportion of participants providing receipts varied primarily by consumer traffic volume, suggesting that individual patron factors were not major determinants of participation rates. Overall, this report's findings suggest that when fast-food chain patrons are provided calorie information prominently prior to purchase, many will see it and use it to reduce their caloric intake.

Given the frequency of fast-food consumption, even modest reductions in calories (e.g., 50 calories per meal) could significantly reduce population-level caloric intake. ^{11, 12} However, the vast majority of patrons purchasing fast-food do not have ready access to the information needed to make healthy decisions. In December 2006, the New York City Board of Health mandated posting calorie information on restaurant menus and menu boards. This mandate was legally challenged and overturned in September, 2007. In October 2007, the New York City Board of Health proposed a new mandate addressing the concerns raised by the legal ruling. Public health authorities and restaurant establishments should consider interventions to make calorie information more prominently visible at point of purchase in order to increase information, reduce calorie intake, and reduce obesity-related morbidity and mortality.

CONCLUSIONS

The per-meal caloric content of fast-food purchases is high. Although fast-food restaurants report publishing nutritional information publicly, most chains' current methods of providing this information to patrons are ineffective. Placement of calorie information at point of purchase is more effective and may be associated with lower calorie purchases among consumers reporting seeing information.

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			Calories		% Patrons Purchasing				
Chain Type ^a	N Sites Sampled	N Valid Receipts	Mean	SE		≥1,000 calories		≥1,250 calories	3
Burgers	75	3857	856.8	10.8		38.6		16.5	
Chicken	14	649	931.3	20.7		47.5		18.0	
Pizza	17	272	765.8	115.0		20.6		15.1	
Sandwiches	49	1989	733.6	16.2		20.0		8.8	
Tex-Mex	3	96	899.7	60.1		41.7		17.7	
Co-located chains	9	455	860.9	24.0		35.6		16.9	
Total	167	7318	827.4	10.7		33.5		14.5	
			;	Subway Patr	ons Only				
					р		р		р
All	47	1830	749.2	13.8		21.3		9.4	
Did not see calorie information ^b		1237	765.5	16.6	<0.01	23.0	<0.01	7.4	<0.05
Saw calorie information b		568	713.8	15.5		17.4		10.3	
Had effect ^c		200	646.9	19.4	<0.001	12.0	< 0.02	4.0	< 0.03

^a Chain Type definitions: **Burger**: Burger King, McDonald's, Wendy's; **Chicken**: Kentucky Fried Chicken (KFC), Popeye's; **Pizza**: Domino's, Papa John's, Pizza Hut; **Sandwiches**: Au Bon Pain, Subway; **Tex-Mex**: Taco Bell; **Co-located**: KFC/Taco Bell, Pizza Hut/Taco Bell, KFC/Pizza Hut, Burger King/Popeye's

17.0

20.2

341

745.8

No effect c

9.1

b Self-reported Self-reported

Disclosure of Financial Information

David B. Allison - Printed: 1/5/2005 11:06 AM

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Air Canada

Alabama Agricultural Land Grant Alliance (AALGA)

Allegheny University

American Bakers' Association

American Dietetic Association

American Oil Chemists Society

American Psychological Association

American Society for Parentaral and Enteral Nutrition

Amgen

Amylin

Archer Daniels Midland

Autogen

Bayer

BioAnalogics

Biogen

Biognosis

BodyStat

Bristol Myers Squibb/Mead Johnson

Campbell Soup Company

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Federal Bureau of Prisons

Federal Trade Commission (FTC)

Federation of American Societies of Experimental Biology

Fertin Pharma A/S

Fisons Corporation

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Food and Drug Administration

Gardiner-Caldwell Communications Ltd

Gemini

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Genentech

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Genome Canada

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Genset

Gerber Foundation

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Grey Health Care Group

Health Learning Systems

Henry A. Murray Research Center at Radcliffe College

Hershey

Hoffman La-Roche

IBC UK Conferences

Institute for the Future

International Association for the Study of Obesity

International Food Information Council

International Life Sciences Institute

Interneuron

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ISL Healthcare Group

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Neurogen

New York State Department of Health

Noonan/Rosso Communications, Inc.

North American Association for the Study of Obesity

North Atlantic Treaty Organization

NutraSystems, Inc.

Nutratech, Inc.

Nutricia

NutriPharma (Scan Diet; Nutralet)

Original Marketing, Inc.

Ortho-McNeil Pharmaceuticals

Parenti, Falk, Waas, Hernandez & Cortina, Attorneys at Law

PAREXEL International Corporation

Paterson, MacDougall, a Toronto, Canada law firm

Pepsi-Cola

Pfizer Central Research

Pinnacle

Porter Novelli

Proctor & Gamble

Queens University, Canada

Rand Corporation

Research Testing Laboratories

Rexall

RW Johnson Pharmaceutical Research Institute

Schering-Plough

Sequana

Servier Amerique

Slim America

SlimFast Foods Company

Spadoro & Hilson, Attorneys at Law

Sugar Association

SuperGen, Inc

Tanita

Terrapin Technologies

The Cortland Group

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Variagenics

Veteran's Administration

VimRx Pharmaceuticals

W.B. Saunders Publishing Co.

Weight Control Digest

Weight Watchers International

Wellcome Trust Wheat Foods Council

Wilentz, Goldman, & Spitzer, Attorneys at Law

Wyeth-Ayerst

Zeneca Pharmaceuticals

David B. Allison, Ph.D.

Sent: Fri 11/16/2007 5:01 PM

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Resolution Comments

From:

Jessica Geslani [jgeslani@aapdistrictii.com]

To:

Resolution Comments:

Cc:

bramjet@aol.com; George Dunket

Subject:

AAP District II LOS - Proposed Amendment 81.50

Attachments:

AAP.81.50.111607.pdf(151KB)

Attached please find a LOS from AAP District II for proposed amendment 81.50.

Thank you.

Sincerely,

Jessica Gestani

District Administrative Coordinator

Executive Director, NY Chapter 2, NY Chapter 3

American Academy of Pediatrics

(516) 326-0310

American Academy of Pediatrics



39

DISTRICT II NEW YORK STATE

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Administrative Coordinator Jessica Geslani Email; jgeslani@aap.org

☐ 420 Lakeville Road Suite 244 Lake Success, NY 11042 Phone: 516/326-0310 Fax: 516/326-0316

http://www.aapdistrictii.org

November 16, 2007

Thomas R. Frieden, MD, MPH Commissioner of Health New York City Department of Health and Mental Hygiene 125 Worth Street New York, NY 10013

Dear Dr. Frieden:

The American Academy of Pediatrics enthusiastically supported the amendment to the New York City Health Code (81.50) that mandates the posting of the caloric content of foods in certain restaurants when it was proposed last year and enthusiastically supports the current revision. We were saddened by the efforts of the New York Restaurant Association to prevent this regulation from passing. We believe that the posting of caloric information in restaurants would be an effective weapon in the battle against childhood obesity. As the AAP has asserted in a policy statement "Prevention of overweight is critical, because longterm outcome data for successful treatment approaches are limited." We agree that "there is no one cause of obesity" and thus we must address each contributing factor in our effort to prevent the current crisis from becoming a catastrophe. We have to address the role that schools, the media, the environment, genetics and, yes, the food that is eaten away from home in restaurants play in engendering obesity in our children. We believe that this amendment does provide a tool that will enable parents and adolescents to make healthier choices when they cat out.

Critics have asserted that "The City can make no case that the Regulation will have a plausible effect on obesity levels in the City." Although such an effect has not been definitively proven, there are research data that suggest that providing caloric content at the time of ordering does influence the purchasers' choices. Since the causes of the obesity epidemic are multiple, correcting only one factor may not demonstrably decrease the problem of overweight children, but, as a part of an overall societal change, will contribute to diminishing this growing health problem.

As pediatricians practicing in New York City, we encounter, on a daily basis, overweight children who are suffering the medical and psychological consequences of obesity. As pediatricians we are committed to the concept of preventive care whether we are providing immunizations to prevent infectious diseases, anticipatory guidance to prevent childhood injury or recommending fluoride treatment to prevent dental caries. Offering information about caloric content in city restaurants at the time of purchase—not afterward on a napkin or placemat and not prior to even entering the restaurant on a web site—is a similar preventive measure.

We applaud the New York City Department of Health and Mental Hygiene for promulgatingthis amendment and fervently hope that it is adopted as law.

Sincerely,

Chang alchaete Henry Schaeffer, MD, FAAP

Chair, District II (New York State), AAP

Ishvar S. Patel, MD, FAAP President, NY Chapter 2, AAP

Y Syllapse

Abraham Jelin, MD, FAAP Vice President, NY Chapter 2, AAP Co-Chair, NYC Youth Advocacy Com.

NY Chapters 2 and 3, AAP

Sheila L. Palevsky MD, MPH, FAAP President, NY Chapter 3, AAP

Andrew Racine, MD, PhD, FAAP Vice President, NY Chapter 3, AAP Co-Chair, NYC Youth Advocacy Com.

NY Chapters 2 and 3, AAP



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Resolution Comments

From:

Amy J. Schwartz [ajschwartz@nyc.rr.com]

Sent: Mon 11/26/2007 12:24 PM

To:

C¢:

Resolution Comments

Subject:

11-27 Testimony for 81.50

Attachments: 381.50 Calorie Posting Testimony 11-27.doc(173KB)

Please see the attached written comments to be delivered in person at the public hearing on Section 81.50 scheduled for November 27th.

I will also be testifying at the public hearing tomorrow.

Thank you. Please contact me if you have any questions.

Amy J. Schwartz, MPA **Executive Director** Public Health Association of New York City 1710 First Avenue, Suite 282 New York, NY 10128 (212) 722-1063 tel (212) 722-0726 fax ajschwartz@nyc.rr.com personal info@phanyc.org www.phanyc.org



PUBLIC HEALTH ASSOCIATION OF NEW YORK CITY

1710 First Avenue, Suite 282 New York, NY 10128 (212) 722-1063 tel. • fax: 212-722-0726

Email: info@phanvc.org www.phanyc.org





ORK STATE PUBLIC HEALTH ASSOCIATION

150 State Street, 4th Floor/SCAA Suite Albany, NY 12207

(518) 427-5835 Email: info@nyspha.org

www.nyspha.org

Public Health Association of New York City New York State Association of Public Health

Statement for the NYC Department of Health and Mental Hygiene Board of Health Public Hearing on Notice of Intention to Repeal and Reenact §81.50 of the New York City Health Code November 27, 2007

Good morning. My name is Amy J. Schwartz, and I am the Executive Director of the Public Health Association of New York City. I am pleased to deliver this testimony of support on behalf of both PHANYC and the New York State Public Health Association, each an independent affiliate of the American Public Health Association, the national organization of public health professionals. Together, we are the largest representation of public health professionals devoted to promoting and protecting the public's health throughout New York City and New York State. We would also like to recognize and thank the New York State Healthy Eating and Physical Activity Alliance for contributing to this testimony.

The Public Health Association of New York City and the New York State Public Health Association enthusiastically support New York City's proposal to repeal, modify and reenact §81.50: Calorie Posting.

Growing rates of obesity and its associated epidemic of obesity threaten to undermine health gains made in New York City in recent years. Some experts even warn that absent intervention, the rising rates of obesity and diabetes may shorten the lifespan of our children and grandchildren. While no single intervention can by itself reverse these alarming trends, each specific measure helps to create an environment that supports efforts by New Yorkers to reduce their consumption of unhealthy food. Posting calories in chain restaurants will help consumers make more informed, healthier choices for themselves and their families. It is a common sense measure that poses no risk to anyone and imposes only minimal responsibilities on food service businesses that have long profited from promoting unhealthy foods.

Since 1977, adult caloric intake has increased 200 calories per day. Recent research reports show that chain restaurants are an important and growing source of the types of food most often associated with increased caloric intake and obesity. Because people consume one-third of their daily calories away from home and because chain restaurants are the most popular destination for diners, it's important that calories be posted dearly and prominently at chain restaurants.

Studies have shown that providing easy-to-access calorie information at point of purchase affects the choice people make, causing them to consume 15% fewer calories. By providing calorie information prominently at New York City chain restaurants, the proposed legislation will help reduce the incidence of obesity and other health problems caused by poor nutrition, thus benefiting New York City children, their parents and the tax payers who now pay the medical costs associated with obesity. Thus, on behalf of New York's public health—professionals the Public Health Association of New York City and the New York State Public Health Association enthusiastically support §81.50: Calorie Posting, and support New York City's efforts to protect the health and well-being of its residents.

For more information on this testimony or the Public Health Association of New York City, please contact Amy J. Schwartz, PHANYC Executive Director at (212) 722-1063 or info@phanyc.org, or Nicholas Freudenberg, Distinguished Professor of Public Health, Hunter College and PHANYC President at infreuden@hunter.cuny.edu. For additional information on diabetes, obesity and physical activity, please see our policy reports: "Reversing the Diabetes and Obesity Epidemics in New York City", "Steps to Get New Yorkers Moving: Policy recommendations to improve opportunities for physical activity"and "Nutrition and Physical Activity in New York City: Defining a Common Policy Agenda" at www.phanyc.org, publications page.

For more information on the New York State Public Health Association, please contact (518) 427-5835 www.nyspha.org or info@nyspha.org.

Page I of I

58

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Resolution Comments

From:

Michele.Bonan@Cancer.org [Michele.Bonan@Cancelleg] Section

To:

Resolution Comments

Cc:

Subject:

*Resubmitting testimony with Additional Support for HC 81.50 - calorieposting

Attachments:

Final ACS Menu Labeling testimony NYC 11.14.07.pdf(307KB)

To: Rena Bryant, Department of Health and Mental Hygiene, Board of Health

Via Email: RESOLUTIONCOMMENTS@HEALTH.NYC.GOV

Via Fax: 212-788-4315

Re: Resubmitting testimony with Additional Support for HC 81.50 - calorie

posting

Ms. Bryant;

Yesterday, I submitted testimony from the American Cancer Society, Eastern Division in support of the repeal and reenactment of Section 81.50 HC. However, we recently learned that the American Cancer Society Cancer Action Network (our National Office) would also like to weigh in support of this rule. Because of this additional support, we would like to replace our earlier submission with the attached updated version that references both organizations. Please include this version for the record.

Feel free to contact me if there is any confusion, at 917-439-0026.

Thank you, Michele Bonan

(See attached file: Final ACS Menu Labeling testimony NYC 11.14.07.pdf)

Please note new address

Michele Bonan Regional Advocacy Director American Cancer Society, Eastern Division 132 West 32nd Street, New York, NY 10001

ph: 212.492.8404 cell: 917-439-0026 fax: 212.237.3855



To:

Rena Bryant

Department of Health and Mental Hygiene, Board of Health

Via Fax:

212-788-4315

Re:

Testimony of the American Cancer Society, Eastern Division (NY and NJ)

and the American Cancer Society Cancer Action Network

In Support of Proposed Amendment (§81.50) to the New York City Health Code

Requiring Calorie Labeling in Food Service Establishments

Date:

November 27, 2007

The American Cancer Society (ACS), Fastern Division and American Cancer Society Cancer Action Network applicates the efforts of the New York City Board of Health in proposing this important policy initiative to help address the urgent problem of obesity.

Obesity is a major epidemic with serious implications for the health and economic status of New York City and our country. While most know that excess pounds raise the risk of heart disease, hypertension, diabetes, stroke, and other fatal health problems, few are aware of the link between obesity and cancer. It is currently estimated that 14% of cancer deaths among males and 20% of deaths among females are attributed to obesity (Calle et al., 2003). Consequently, more than 2250 New York City residents die each year from preventable obesity-related cancers. National health care expenditures are estimated at \$70 to \$100 billion per year and are expected to grow with the increasing rates of overweight and obesity (Olshansky, 2005). Healthcare costs are 56% higher for an obese person compared to a normal weight person. This puts significant financial pressure on the Medicaid program and the New York City budget since obesity is approximately twice as high in low-income populations compared to higher income groups (Willet and Domolky, 2003). The Centers for Disease Control and Prevention's Pediatric Nutrition Surveillance Study of 2002 found that New York State has the 3rd highest rate of low-income overweight children in the country.

Every five years the American Cancer Society issues Nutrition and Physical Activity Contained for Cancer Prevention. A national panel of experts in cancer research, prevention, epidemicles, public health, and policy develop the Guidelines, and as such, they represent the most current scientific evidence related to dictary and activity patterns and cancer risk. Given the mounting evidence regarding obesity and cancer, the current Guidelines, released September 28, 2006 (listed below), reflect an increased emphasis on weight control.

ACS Recommendations for Individual Choices

- 1. Maintain a healthy weight throughout life.
 - · Balance caloric intake with physical activity.
 - · Avoid excessive weight gain throughout the life cycle.
 - · Achieve and maintain a healthy weight if currently overweight or obese.
- 2. Adopt a physically active lifestyle.
- 3. Consume a healthy diet, with an emphasis on plant sources.
- 4. If you drink alcoholic beverages, limit consumption,

Community efforts are also essential to create a social environment that promotes healthy food choices and physical activity. Therefore, the ACS Guidelines also include a key recommendation for community action to accompany the four recommendations for individual choices to reduce cancer risk. This recommendation for community action recognizes that a supportive social and physical environment is indispensable if individuals at all levels of society are to have genuine opportunities to choose healthy behaviors.

ACS Recommendations for Community Action

Public, private, and community organizations should work to create social and physical environments that support the adoption and maintenance of healthful nutrition and physical activity behaviors.

• Increase access to healthful foods in schools, worksites, and communities.

The American Cancer Society supports initiatives that empower individuals to make healthier choices, and therefore supports the repeal and reenactment of §81.50 to the New York City Health Code. This proposal to require caloric labeling is consistent with the ACS Guidelines



regarding community action and will help create the environmental changes needed to impact the current trend in obesity. An individual cannot avoid health risks unless they know a torre they аге.

Like other voluntary health organizations, ACS disseminates nutrition guidelines in order to empower individuals with information to make informed decisions about their health. However, in order for an individual to make an informed decision about what they eat, it is important that nutritional information be readily available when the purchase decisions are being made. People have grown accustomed to having nutrition information on packaged foods in supermarkets (3/4 of people report using labels) and they want and deserve to have it on menus as well. A recent, industry-sponsored poll showed that 83% of Americans want restaurants to provide nutrition information. Menu labeling legislation has been introduced in 17 states and cities across the country, as well as in the U.S. Congress.

In addition to providing consumers with information to help them make informed decisions. menu labeling would provide an incentive for restaurants to add new menu items and reformulate existing options to reduce the calories. We saw this happen when Nutrition Facts labels went on packaged foods in 1994 and we see it now with companies lowering or eliminating trans fats in response to the FDA requiring trans fat labeling. The food industry may think twice about selling a quad burger (4 beef patties, 4 slices of cheese, and 8 slices of bacon), as a leading fast food company does, if they have to show the 1,000 calorie price tag that goes along with it.

With approximately half of the food dollar now being spent away from home (almost doubling since 1970), it is appropriate to make caloric information visible in restaurants, especially where foods are typically higher in fat, calories, and larger portion sizes prevail (Finkelstein et al. 2004). If implemented, most fast food chains in New York City will need to post the caloric content of their menu offerings. This is critically important since one study found that children who are fast food obtained from 29 percent to 38 percent of their total energy intake from that source and ate more total fat, more saturated fat, more total carbohydrate, more added sugars, more sweetened beverages, less fluid milk, and fewer fruits and non-starchy vegetables than those who did not. The same study estimated that on a typical day nearly one third of children in the U.S. eat fast food (adolescents visit a fast-food outlet twice per week on average) and that

Page 11 of 18

these extra calories pack on an extra six pounds per child per year. Parents especially deserve to have more easily viewed caloric information to compare menu items and information for all, food purchases outside the home.

Further, people need calorie labeling information because it is difficult to estimate the cult deeple restaurant meals. A study conducted by the Center for Science in the Public Interest and New York University found that even well-trained nutrition professionals couldn't estimate the caloric content of typical restaurant meals. They consistently underestimated calorie amounts and the underestimates were substantial - by 200 to 600 calories. For example, when shown a display of a typical dinner house hamburger and onion rings, the dictitions estimated that it had 865 calories, when it actually contained about 1,500 calories. If trained nutrition professionals can't estimate the calories in restaurant meals, the average consumer doesn't stand a chance. Of our die intense market research applied to the development of new food products, it is likely that fast food companies understand that few consumers can accurately estimate calories.

The current voluntary provision of nutrition information by many restaurants, although inconsistently offered, does show that providing food composition data is frasilite, practical, affordable, and wanted by the consumer. Although having the information on a web-ite or somewhere behind the counter is a good start, it is inadequate. Consumers should be able to at least see the information most related to weight gain (calories) when ordering their food and drinks. A patron should not be expected to request the information or go searching to view the caloric content of the food somewhere else like a poster on the wall with tiny print. The increased flexibility by the health department is a positive change that should be less burdensome for the industry to comply.

We have seen in the fight against tobacco the substantial benefits of taking an aggressive policybased approach that makes it easier to pursue healthier behaviors while creating barriers to unhealthy practices. In the early years of tobacco control, some states such as California and Massachusetts implemented a variety of population-based interventions before the efficacy was clear. It was only when these initial "real-world" efforts, were evaluated and proven successful, that led to best practices being disseminated to other states. Like lessons learned in tobacco, strategies such as the proposed labeling provision, should be part of a comprehensive approach

to address obesity and the many factors contributing to the problem. Fortunately, New York City has already implemented other citywide attack or with improving the enterty. In program and enhancing nutrition and physical activity regulations in daycare settings

Finally, the National Academies' Institute of Medicine recommends that restaurant chains "provide calorie content and other key nutrition information on menus and packaging that is prominently visible at point of choice and use" (2006). The Food and Drug Administration, Surgeon General, U.S. Department of Health and Human Services, and the 2007 President's Cancer Panel also recommend providing point of purchase nutrition information at restaurants as a strategy to reduce caloric intake and help combat the worsening obesity crisis.

The American Cancer Society supports the significant step proposed by the City of New York as part of a comprehensive approach to addressing obesity, and we believe it is likely to promote reductions in obesity and cancer. Therefore, we strongly urge the adoption of Proposed Amendment §81.50 to the New York City Health Code.





Michael D. Maves, MD, MBA, Executive Vice 8:

November 27, 2007

Ms. Rena Bryant Secretary to the New York City Board of Health 125 Worth Street CN-31 New York, New York 10013

Dear Ms. Bryant:

On behalf of the American Medical Association's (AMA) physician and resident members we share New York City's disappointment with the recent decision in New York State. Restaurant Association v. New York City Board of Health, which struck down the health code regulation requiring restaurants that have analyzed and publicized the coloric content of their standard menu items to list that information on menus and menu boards. In the ruling, however, the judge provided a framework for the New York Board of Health to restaute without violating federal law. We applied the of the federal court's guidelines.

AMA policy strongly supports rules requiring restaurants that have items common to multiple locations to provide standard nutrition labels for all applicable items, available to public viewing. By increasing consumers' awareness of what they eat, it is our hope that consumers will be more likely to choose healthy foods and that they will think twice about eating unhealthy foods.

The revised regulation will enable consumers to make more informed health choice. We urge the New York City Council to pass the hap retained will

Sincerely,

Michael D. Maves, MD, MBA

cc: Rick Abrams

American Medical Association 515 North State Street Chicago Illinois 60610 phone: 312 464 5000 fax: 312 464 4184 web: www.ama-assn.org

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Resolution Comments

F: To:

Resel. Mon. Comin. Linus

Cc:

Subject:

Comments on Menu Labeling proposal

Attachments: [1] Ms. Rena Bryant, NYC Board of Health Letter., ur(229KB)

Ms. Bryant:

Please see the attached letter from Dr. Michael Maves, CEO of the American Medical Association in support of the menu labeling proposal. Please let me know if you have any questions. Thank you.

Carrie Armour Legislative Attorney AMA Advocacy Resource Center (312) 464-4039 (312) 464-4961 FAX carrie.armour@ama-assn.org

American Heart Association Testimony: Board of Health Proposal to Reenact §81.50 of the New York City Health Code

November 27, 2007

Good afternoon (morning) Commissioner Frieden and Members of the Board. My name is Dr. Judith Wylie-Rosett, and I am speaking today on behalf of the American Heart Association. I would like to thank you for allowing us to testify and for the opportunity to express our support for the reenactment of §81.50 of the New York City Health Code.

The American Heart Association is the largest voluntary organization in the world dedicated to the reduction of disability and death due to hear; disease and stroke - the number one and three causes of death nationally. To achieve this mission, we fund research; develop benchmark treatment guidelines; implement educational and awareness programs; and advocate for policies that will reduce the incidence of cardiovascular disease (CVD).

The American Heart Association supports providing calorie information on menus and menu boards at the point-of-purchase, as outlined in §81.50, in order to allow consumers to make more informed choices about the food they purchase in restaurants. This policy is an important part of a comprehensive approach to addressing New York City's obesity epidemic and the concurrent rise in risk levels for cardiovascular and other chronic diseases.

Obesity is of particular concern with respect to cardiovascular disease, because it raises blood cholesterol and triglyceride levels; lowers HDL "good" cholesterol, which is linked with lower heart disease and stroke risk; raises blood pressure levels; and can induce diabetes. Even when none of these adverse effects are present, obesity by itself increases the risk of heart disease. Unfortunately, this increased risk of cardiovascular disease begins early in life. Obese children between the ages of 5 and 10 are more than twice as likely as their peers to present at least one risk factor for cardiovascular disease, and a quarter of obese children will present at least two risk factors for CVD.

The obesity rate in New York City has risen significantly over the past few decades, and it continues to climb. One of every five residents is obese. Among both minority and low-income residents, the rate of obesity is higher still; approximately one-in-four New Yorkers in these populations is now obese. And New York City's children are not immune to this epidemic. By kindergarten, approximately one-fifth of our children are obese and a further 19% are overweight.

For the first time in history, today's children are predicted to have a shorter life expectancy than their parents. If current trends continue, the Institute of Medicine expects poor nutrition and physical inactivity to surpass tobacco as the leading underlying cause of preventable deaths in the United States by the year 2010.

Fortunately, we know that obesity and the risk of concomitant disease (whether heart disease or other chronic disease) can be both prevented and treated through healthy eating and physical activity. The root cause of obesity is generally understood to be an imbalance in caloric intake and energy expenditure, in other words, taking in more calories than are used in physical activity and daily life. If individuals are to maintain a healthy weight, it is vital that they are educated about their nutritional needs and have access to information about how many calories are contained in the food and beverages they consume.

For well over a decade, nutrition labeling regulations at the federal level have allowed individuals to evaluate the nutritional content of most foods purchased for home consumption. Seventy to 85% of the American adolescent, college, and adult populations read food labels at least sometimes, and studies have shown that individuals who read food labels while shopping tend to have diets lower in fat and higher in fruit and vegetable consumption when compared with those who do not read food labels.

Unfortunately, when it comes to foods purchased outside the home, consumers currently have little, if any, nutritional information available at the point of service. At the same time, New York City residents are consuming an ever greater number of meals outside the home, making the posting of calorie information at the point-of-purchase in

restaurants more important than ever. People typically underestimate the calorie content of the foods they consume, and restaurant foods tend to be served in larger portions and are often higher in calories than foods prepared at home. Not surprisingly, studies show that eating out more frequently is associated with obesity and higher body mass index (BMI). It is clear that if New Yorkers are to make healthy choices in restaurant settings, they must have access to accurate calorie information at the point of service.

While the American Heart Association acknowledges that there is not yet conclusive data showing that consumers will adjust their behavior in response to menu labeling, there are several published studies that suggest this is, in fact, the case. A 2006 study published in the American Journal of Public Health concluded that when objective, quantitative nutrition information was provided, consumers had more unfavorable attitudes towards the less healthful items and their purchase intentions for those items were significantly diminished. A similar conclusion was reached as far back as 1976, when a study in a cafeteria setting concluded that signs indicating the calorie content of available foods significantly decreased the number of calories purchased.

Based on the preliminary data, the American Heart Association believes that providing calorie information at the point-of-service in restaurants will result in consumers purchasing fewer calories and a consequent reduction in the rate of obesity and concomitant disease. Our recommendations for policies on menu labeling are as follows:

- 1) We endorse requirements for chain restaurants to post calorie information on menus and menu boards at the point-of-purchase. While it would be ideal to have calorie labeling more widely available, the American Heart Association acknowledges that for casual and fine dining restaurants where preparation and menu items may vary substantially, the provision of calorie information would currently be difficult and potentially costly.
- 2) We encourage provisions allowing restaurants to provide a calorie range in instances where consumer choice or flavor variations make an exact count impractical.

- We support continuing research into the most effective informational formats for menu labeling.
- 4) And, finally, we recommend that a consumer education campaign on individual calorie requirements be planned to coincide with the implementation of any menu labeling requirements.

The American Heart Association offers its enthusiastic support for the Board's proposal to reenact §81.50 of the New York City Health Code. We believe it strikes a very fair balance between the informational needs of consumers and the costs associated with its implementation.

Our desired outcome is that all New York City residents have the information they need to make informed choices about the food and beverages they consume. These regulations are not about controlling what consumers choose to order or what restaurants make available for purchase. Rather, they will empower consumers and give them more choices by providing additional information about the menu items on offer. Access to nutritional information is vital if we are to address our national obesity epidemic and the concurrent rise in cardiovascular and other chronic diseases.

Thank you, once again, for your time. The American Heart Association looks forward to continuing to work with you to reduce the rate of obesity and resultant chronic disease in New York City.



Health Bulletins on issues of pressing interest to all New

How to Lose

And Keep It Off

CARE

Health Bulletin #51: How To Lose Weight



How to Lose Weight

Being overweight or obese raises your risk of many serious health problems, including diabetes, heart disease, stroke, high blood pressure, arthritis, and even cancer. But losing even a few pounds can reduce these risks!

Use more calories than you eat.

- One pound = 3,500 calories.
 - If you eat 3,500 calories more than you burn, you gain a pound.
 - If you burn 3,500 calories more than you eat, you lose a pound.
- The exact number of calories a person needs depends on age, sex, and activity level.
 - Most men ages 41 to 60 need about 2,200 calories a day.
 - Most women the same age need fewer between 1,600 and 1,800 a day.

• To find out what you need, go to www.mypyramid.gov.

Do it for life.

- To lose weight and keep it off, don't suffer and DON'T DO "FAD" DIETS!
- Make changes you enjoy and can stick with long-term.



10 Weight-Loss Tips

1. Take your time.

se 1:08-cv-01000-RJH

- Aim to lose only 1 or 2 pounds a week. People who lose weight faster are more likely to gain it back.
- Don't be tempted by "fad" diets and drugs. They don't work for long, and some are dangerous.

2. Pay attention to what you eat and drink.

- Keep a daily food diary for a while. Most people eat out of habit and are unaware of how much they consume.
- Don't eat in front of the TV. Get a real plate and sit down at the table.
- Eat slowly. It takes about 20 minutes to start feeling full. People who eat too fast often eat too much.

3. Watch your empty-beverage calories.

- One regular can of soda, or one sugary drink has about 150 EMPTY calories (no nutritional value).
- One less sugar-sweetened drink a day = a 15-lb. weight loss in a year.
- Drink water, unsweetened tea, or low-fat milk instead of regular soda and other sugar-sweetened drinks.

NYC Water Get Your Fill

4. Prepare more meals at home.

- It's easier to know and control what you eat when you prepare your own food.
- Home-cooked meals are usually healthier and less expensive than eating out.
- Read Nutrition Facts labels when you shop.

5. Choose carefully when eating out.

- To lose weight, eat out less.
- Some entrees and large fast-food meals have more than 1,500 calories -- almost enough for a whole day!
- When you *do* eat out, watch out for large portions. Split an order, or take half of it home.
- Choose healthier items, such as salads (but watch the dressing!)



That Really Work

6. Eat more fruits and vegetables.

- Aim for 5 to 9 servings a day.
- They help keep you healthy and fill you up on very few calories.

7. Feel FULL on fewer calories.

 Make smarter choices. You could have 8 to 10 servings of fruits and vegetables for every ONE fast-food taco salad (800 calories).



- Choose high-fiber foods that fill you up: fruits, vegetables, beans, lentils, and whole-grain cereals, breads, and pasta.
- Have a broth-based soup or green salad at the start of a meal.
- Drink plenty of water at least 8 glasses a day.

8. Choose healthier snacks.

- Snack on fruits and vegetables instead of candy, cookies, and chips.
- Try pretzels, low-fat popcorn, or low-fat frozen yogurt.

9. Don't skip breakfast.

- People who eat breakfast lose weight easier.
- Skipping meals makes you hungrier and more likely to overeat.

10. Get moving!

 Physical activity improves mood and makes you healthier – even if you don't lose weight.

 Get at least 30 minutes of moderate physical activity, such as brisk walk, at least 5 days a week.

- You don't have to join a gym or buy a lot of expensive equipment.
- Just walking burns calories, improves heart health, and strengthens muscles.
- Get off the bus or subway one stop early and walk the rest of the way.
- Take the stairs instead of the elevator.



Small Changes That Can Help You Lose Weight

If you usually	Instead you can	If you make this change	lose up to this many pounds a year	
Use the elevator or escalator	Climb stairs for 2 minutes	Every day	2	
Use α tαblespoon of mayonnaise on your sandwich	⊘ Use mustard	3 times a week	4	
Eat a large order of fast food fries	Substitute a small order of fast food fries	Once a week	5	
Watch a lot of TV	Ø Do α little housework	1/2 hour a day	5	
Drink an 8-oz. glass of whole milk	Drink an 8-oz. glass of non-fat milk	Once a day	6	
Have 2 drinks sitting at the bar for an hour	Order 1 drink and dance for an hour	Once a week	6	
Drive or take a taxi, bus or subway	Walk briskly for 20 minutes	Every day	7	
Snack on a 2-oz. chocolate bar	Have a piece of fruit	Twice a week	7	
Nrink α 16-oz. lαtte with whole milk	Orink α 16-oz. latte with non-fat milk	Every day	10	
Eat a 3-egg cheese omelet with bacon, toast and hash browns	Have a bowl of cereal with non-fat milk for breakfast	Once a week	11	
Eat α pint of ice cream every week	Substitute α half-pint of sorbet	Every week	12	
Drink a can of regular soda	Have a glass of water	Once a day	15	

More Information

- New York City Department of Health and Mental Hygiene: nyc.gov/heart or call 311 and ask for "Healthy Heart"
- Free NYC fitness programs: nyc.gov/parks or call 311 and ask for "Fitness."
- Weight loss: www.fda.gov/loseweight
- Physical activity: www.cdc.gov/nccdphp/dnpa/physical/index.htm
- Healthy diet: www.mypyramid.gov



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PREVENTING AND MANAGING **OVERWEIGHT AND OBESITY IN ADULTS**

- Assess weight status periodically by weighing patients and calculating their body mass index (BMI).
- Develop a realistic weight-loss plan with your patients; focus on a reduced-calorie diet, regular physical activity, and behavioral support.
- Promote healthy lifestyle choices for life-long weight management.

verweight and obesity are epidemic in New York City (NYC) and across the country. About two thirds of the US population are overweight or obese,1 including more than half (about 3 million) of the adults in NYC. More than 100,000 deaths a year nationwide are directly attributed to obesity,² and increased body weight is associated with higher all-cause mortality.3 The key modifiable behavioral factors in obesity—unhealthy diet and physical inactivity are second only to smoking as causes of premature death in the US.4

Being overweight or obese increases the risk of type 2 diabetes, heart disease, stroke, gall bladder disease, osteoarthritis, sleep apnea, respiratory problems, and colon, breast, endometrial, and prostate cancers.³ Other health consequences include compromised psychological well-being along with social stigmatization and discrimination.3

Obesity-Related Disparities in New York City⁶

- In NYC, women are more likely than men to be obese (23% vs. 20%).
- The poorest New Yorkers are more obese than the wealthiest (29% vs. 16%).
- Black and Hispanic New Yorkers of all income levels are more likely to be obese than white New Yorkers. Even among residents with household incomes ≥\$50,000, nearly twice as many blacks and Hispanics are obese than whites (23% vs. 12%).
- Poorer New Yorkers are less likely to exercise, regardless of race/ethnicity.

The dramatic doubling in obesity rates among US adults—from 15% to 32% between 1971 and 2004—cannot be explained by changes in genetic factors. Rather, changes in nutrition, physical activity, and environmental factors are key contributors to this epidemic. Weight gaininducing behaviors include sedentary lifestyle, consuming a diet high in calories, relying on food prepared and eaten outside the home, and excessive intake of high-calorie beverages. Environmental factors that influence these behaviors include poverty, heavy marketing of unhealthy foods and large portion sizes, and the construction of neighborhoods that discourage physical activity.3

Weight gain occurs incrementally over time; between 1990 and 2000, US adults gained an average of 1 pound per year. 5 Given this insidious process, it is critical that clinicians carefully monitor weight in their patients and help them modify weight gain-inducing behaviors.



5 Steps to Preventing and Managing Overweight and Obesity in Primary Care

- 1. Assess weight status with body mass index (BMI).
- 2. Assess risk factors and comorbidities.
- Recommend weight loss for overweight and obese patients.
- 4. Assess barriers to weight loss.
- Formulate a weight loss plan that focuses on healthy eating and physical activity.

1. ASSESS WEIGHT STATUS IN ALL ADULTS

Screen all adult patients for overweight and obesity by weighing them and calculating their BMI using the following formula:

 $\frac{\text{Weight (kg)}}{\text{Height (m)}^2} \qquad \text{OR} \qquad \frac{\text{Weight (lbs) x 703}}{\text{Height (inches)}^2}$

An online BMI calculator can be found at: www.nhlbisupport.com/bmi.

Table 1 displays BMI categories; **Figure 1** will help you to quickly assess weight status. Use clinical judgment interpreting the BMI; it may be skewed by edema, high muscularity, muscle wasting, or short stature.

In addition to BMI, a large waist circumference is an independent risk factor among patients with a BMI under 35 kg/m². A waist circumference of >40 inches in men and >35 inches in women increases the risk of type 2 diabetes, dyslipidemia, hypertension, and cardiovascular disease because of excess abdominal fat.⁷

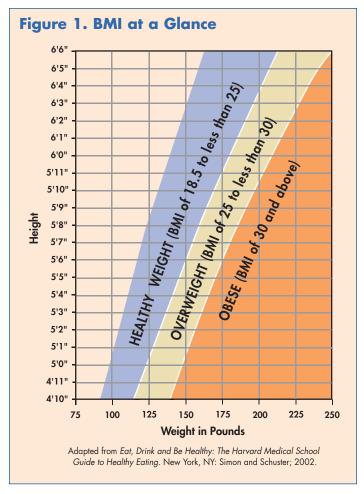
2. ASSESS RISK FACTORS AND COMORBIDITIES

The need for weight loss is particularly critical when other risk factors and/or comorbidities are present. A comprehensive history and physical exam are essential to assess risk factors and comorbidities.

Table 1. Classification fo	r B	3MI7	F
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Classification	BMI Range
Underweight	<18.5 kg/m²
Normal Weight	18.5-24.9 kg/m²
Overweight	25-29.9 kg/m²
Obesity (Class 1)	30-34.9 kg/m²
Obesity (Class 2)	35-39.9 kg/m²

Clinically Severe Obesity (Class 3) ≥40 kg/m²



Identify patients at very high risk for complications, including death. These patients may have:

- Established coronary heart disease, including a history of myocardial infarction, angina, coronary artery surgery, or coronary artery procedures (e.g., angioplasty);
- Presence of other atherosclerotic disease, including peripheral arterial disease, abdominal aortic aneurysm, or symptomatic carotid artery disease;
- Type 2 diabetes;
- · Sleep apnea.

Identify other risk factors that increase risk for cardiovascular disease, including:

- Cigarette smoking;
- Physical inactivity;
- Age—men ≥45 years and women ≥55 years (or postmenopausal);
- Fasting glucose between 110 and 125 mg/dL, or impaired glucose tolerance (OGTT between 140 and 199 mg/dL);
- Hypertension (or blood pressure controlled with medication);
- Low-density lipoprotein (LDL) ≥160 mg/dL;
- High-density lipoprotein (HDL) <35 mg/dL;
- Triglycerides ≥200 mg/dL.

^{*}Some Asian populations may be at increased risk for type 2 diabetes and cardiovascular disease at BMIs <25 kg/m². The cut-off point for increased risk ranges from 22 kg/m² to 25 kg/m² in different Asian populations.⁸

Lifestyle counseling is important for all patients.

Physical activity and healthy eating decrease risks for chronic disease, regardless of weight or weight loss. Counsel all patients to eat a healthy diet and to get at least 30 minutes of moderate-intensity physical activity at least 5 days a week, preferably every day. Moderate-intensity activities, such as brisk walking, bicycling, vacuuming, and gardening cause small increases in breathing or heart rate. Suggest the following weight management tips:

- Avoid high-calorie beverages, including juice.
- Eat less fast food.
- Eat more fruits and vegetables.
- · Limit portion sizes.
- · Incorporate physical activity into daily life.

Other conditions associated with obesity include gynecological abnormalities (e.g., menorrhagia, amenorrhea, polycystic ovarian syndrome), gallstones, osteoarthritis, gout, stress incontinence, and decreased quality of sexual life.¹³

Rule out potential causal factors, such as medical conditions (e.g., hypothyroidism, depression) and current medications, that may induce weight gain. Medications that cause weight gain are particularly common in the treatment of diabetes, mood disorders (e.g., depression, bipolar disorder), and psychotic disorders (e.g., schizophrenia) (see **Table 5**, page 28, for a list of weight gain-inducing medications and alternatives).

3. RECOMMEND WEIGHT LOSS IN OVERWEIGHT AND OBESE PATIENTS

Inform overweight or obese patients of their weight status and recommend weight loss. Provide the patient with information on their risk for chronic disease based on an individual risk assessment (Step 2, page 24) and on the benefits of weight loss. Discuss weight status with sensitivity and attention to potential stigma (Table 2).

Weight loss has many potential benefits. Tell your patients that weight loss can^{7,14}:

- Lower elevated blood pressure;
- Lower elevated levels of total cholesterol, bad cholesterol (LDL), and triglycerides, and raise low levels of good cholesterol (HDL) in those with dyslipidemia;
- Lower elevated blood glucose levels in patients with type 2 diabetes, and prevent or delay the onset of type 2 diabetes in those who do not yet have the disease. In patients with pre-diabetes, a 5% weight loss (about 10–15 lbs) and at least 30 minutes of physical activity 5 days a week reduced the risk of developing diabetes by nearly 60%.¹⁴

In addition to improving a patient's medical profile, weight loss can make a person feel more confident and comfortable in social situations.

4. ASSESS BARRIERS TO WEIGHT LOSS

Weight loss is challenging for most patients. Many will face such obstacles as⁷:

- Lack of motivation;
- Time constraints:
- · Lack of understanding of risks and benefits;
- · Lack of support from family and friends;
- Financial constraints;
- Lack of a feasible plan for making lifestyle changes;
- Lack of access to places for exercise;
- Lack of access to markets that sell healthy foods;
- Family eating patterns;
- Negative attitudes toward physical activity;
- Stigma and weight bias (resulting in inaction).

Understanding these issues and helping patients address potential obstacles will increase the likelihood of success. Even if patients are not ready to lose weight, encourage them to set manageable goals to improve their diet and/or raise their level of physical activity. Healthy behaviors prevent chronic diseases and can help stabilize weight over time.

5. FORMULATE A WEIGHT-LOSS PLAN

The initial goal of weight loss therapy is a 10% reduction in body weight over 6 months. Weight loss should be gradual—1 to 2 pounds, or 1% of body weight, per week. If additional weight needs to be lost after the initial 6-month period, set new targets.⁷

A combination of a reduced-calorie diet, regular moderateto vigorous-intensity physical activity, and support for lifestyle changes is the cornerstone of weight loss and maintenance and the safest strategy for both. Other approaches to weight management include drug regimen changes (if obesity is drug-induced), pharmacotherapy, and weight-loss surgery.

Table 2. Weight Issues Are Sensitive¹⁵

- Weigh patients in a private setting and record weight without judgment or comment.
- Ensure that medical equipment (e.g., gowns, blood pressure cuffs, scales, speculums) is appropriately sized to accommodate obese patients.
- Be sensitive when initiating discussion on weight (e.g., "Being overweight puts you at risk for a number of health problems. Mrs. Smith, could we talk about your weight today?").
- Avoid hurtful or offensive descriptors (e.g., "fatness," "weight problem").
- Use interactive, empathic communication to enhance self-confidence and behavior change (e.g., "How are you feeling about your weight at this time? What are your goals now? What are some practical steps you can take to help meet these goals?").

Treatment		BMI				
	25-26.9 kg/m ²	27-29.9 kg/m ²	30-34.9 kg/m ²	35-39.9 kg/m ²	≥40 kg/m²	
Diet, physical activity, and support for lifestyle change	Yes	Yes	Yes	Yes	Yes	
CONSIDER TREATMENTS BELOW ONLY AFTER FAILURE OF WEIGHT LOSS WITH ADEQUATE LIFESTYLE CHANGES AND IN CONJUNCTION WITH ONGOING LIFESTYLE CHANGES.						
Drug therapy*	No	See below*	See below*	See below*	See below*	

^{*} Consider drug therapy only when patient is at increased medical risk due to weight (e.g., serious comorbidities, such as diabetes or sleep apnea).

Table 3 outlines weight-loss treatment options with consideration given to initial BMI and the presence of serious comorbidities due to weight.

Physical activity

Regular physical activity plays an important role in weight loss and maintenance. Regular exercise also increases cardiorespiratory fitness and may decrease abdominal fat. Even patients who are unable to meet weight targets can significantly decrease their risk of chronic diseases with consistent moderate- to vigorous-intensity physical activity.

Assess patients' current physical activity levels by asking about frequency, duration, and types of physical activity (including walking for transportation). Prescribe a physical activity plan on a prescription pad to convey the importance of physical activity in a weight loss and maintenance plan. 9,17,18

Evaluate patients with high-risk conditions (e.g., diabetes, cardiovascular disease, stroke, uncontrolled hypertension) to determine an appropriate exercise program. The decision to order exercise testing should be based on a patient's age, symptoms, and concomitant risk factors.7 Indications for exercise testing include:

- Known cardiovascular disease, including cardiac disease, peripheral vascular disease, and cerebrovascular disease;
- · Known heart murmur:
- Known pulmonary disease, including chronic obstructive pulmonary disease, asthma, interstitial lung disease, and cystic fibrosis;
- Known metabolic disease, including type 1 or type 2 diabetes, thyroid disorders, and renal or liver disease;
- One or more signs or symptoms suggestive of cardiovascular and pulmonary disease, including pain (or any other anginal equivalent) in the chest, neck, jaw, or arms that may be due to ischemia; shortness of breath at rest or with mild exertion; syncope; orthopnea or paroxysmal nocturnal

dyspnea; ankle edema; palpitations or tachycardia; intermittent claudication; and unusual fatigue or shortness of breath with usual activities.10

At least 30 minutes of moderate-intensity physical activity is recommended a minimum of 5 days a week, preferably every day. For many patients, this level of activity may not be enough to produce significant weight loss and prevent weight regain. For these patients, recommend at least 40 to 60 minutes of moderate- to vigorous-intensity activity 5 or more days a week. 9,11,19 Work with each patient to find a physical activity level that achieves weight control.

Prescribe a physical activity plan on a prescription pad to convey the importance of physical activity.



Daily physical activity does not have to be accomplished all at once. Accumulating activity in 10-minute segments results in health benefits. 9,11 Advise patients to build as much physical activity as possible into their daily routines. Two extra minutes of stair climbing each day can burn the equivalent of 1.6 pounds a year, enough to mitigate the average yearly weight gain in American adults.5 Table 4 describes simple steps patients can take to increase their daily physical activity. For most patients, walking is the most feasible form of physical activity.

Social support (e.g., buddy activities, walking groups) helps people increase physical activity. 20 Provide resources such as fitness resource directories that include information about free and low-cost physical activity programs (Resources).

[†] Recommended criteria for considering bariatric surgery vary, ranging from BMI \geq 35 with comorbidities to BMI \geq 40 to BMI \geq 40 with comorbidities.16

Dietary change

Adherence to a reduced-calorie diet is essential to weight loss. A reduction of 500 to 1,000 calories per day will result in a loss of 1–2 pounds per week. For women, this often means a diet containing 1,000 to 1,200 calories/day; for men, this means 1,200 to 1,600 calories/day.⁷

Assess the patient's current diet to identify opportunities for caloric reduction. It may be helpful to have patients keep a food diary for a few days so that you can identify areas where they can cut back. Common sources of extra calories include:

- High-calorie beverages (non-diet soda, sugar- and fat-laden coffee drinks, fruit drinks and juices, "energy" drinks, alcoholic beverages);
- High-fat and/or high-calorie foods (e.g., "fast food," deep-fried foods, chips, cookies, candy, bagels);
- Large portion sizes (e.g., restaurant meals).

Table 4 describes steps patients can take to reduce daily caloric intake. Addressing simple issues such as beverage choice can be an important first step. If appropriate, refer patients to a dietitian for more in-depth dietary counseling and support.

Table 4. Lifestyle Modifications: Diet and Physical Activity^{7,9,11,19,20}

Physical Activity

To lose weight and to prevent weight regain, work up to at least 40 to 60 minutes of moderate- to vigorous-intensity activity 5 or more days a week.* Daily physical activity can be broken down into 10-minute segments. Every minute of activity burns calories.

Avoid injury and build endurance by starting slowly and increasing physical activity over time. Include as much brisk walking as you can in your daily routine.

- Get off the bus or subway a stop or two early and walk the rest of the way.
- Take the stairs instead of the elevator or escalator.
- Walk for 10 to 20 minutes after every meal.
- Walk in available indoor spaces (e.g., hallways, stairs).

Look for ways to get more physical activity.

- View household chores (vacuuming, raking leaves, running errands) as opportunities to get more physical activity.
- Limit time spent in front of the TV and computer.
- Use TV-viewing time as an opportunity to pedal a stationary bike or walk on a treadmill.
- Put on music and dance.
- Partner up with a buddy for activities, or join a walking group.

Regardless of weight, everyone should get at least 30 minutes of moderate-intensity physical activity at least 5 days a week, preferably every day.

Diet

To lose weight, cut 500 - 1,000 calories/day.

Eat a healthy diet. Look for ways to reduce excess calories.

- Drink water, seltzer, 1% or skim milk, or other low- or no-calorie beverages. Limit or avoid non-diet soda, fruit drinks and juices, high-calorie coffee beverages, alcohol, and 2% or whole milk.
- Limit high-calorie foods.
- Eat less fat: limit fast food, deep-fried foods, and high-fat meats and dairy. Cook with only small amounts of healthy oils (e.g., olive, canola).
- Eat foods high in fiber, such as fruits and vegetables, beans and lentils, and whole grains.
- Snack on fruits and vegetables instead of high-fat and/or high-calorie foods (e.g., chips, candy, cookies).
- · Read food and beverage labels to identify products that are low in calories and fat.

Pay attention to how you eat.

- Control portion size by using smaller plates and bowls.
- Avoid eating in front of the TV.
- Don't skip meals, especially breakfast.
- Prepare more meals at home.

Everyone should eat a moderate, healthy diet to prevent weight gain over time and reduce the risk of chronic disease.

^{*}Moderate-intensity activities cause small increases in breathing or heart rate and include brisk walking, bicycling, vacuuming, and gardening. Vigorous-intensity activities cause large increases in breathing or heart rate (i.e., to the point where it is difficult to hold a conversation). Such activities include running and aerobics.¹¹

Support for lifestyle change

Behavioral support is an important adjunct to a comprehensive weight loss and weight loss maintenance plan. There is evidence that intensive counseling about diet and exercise, together with behavioral interventions aimed at skill development, motivation, and support strategies, produces sustained weight loss in adults who are obese.²¹

After assessing a patient's barriers to weight loss (Step 4, page 25), work with the patient to address those barriers. Help the patient set small, achievable behavioral goals. Many patients want more help with weight management than they receive from their primary care physicians.²² Refer patients who need more support, particularly those at high medical risk, to a behavioral therapist and/or group weight loss program.

Drug regimen considerations

Because some medications can cause weight gain, review all medications a patient is taking and consider weightneutral or weight loss-promoting alternatives (see **Table 5**). If a weight gain-inducing drug cannot be avoided, emphasize the need for regular physical activity and healthy eating. When the weight gain-inducing drug is an antidepressant or mood stabilizer, physical activity can also help relieve symptoms of depression and anxiety and improve mood.²³

Be aware that medications, particularly glycemic and blood pressure control drugs, may need to be modified with any caloric restriction, increased physical activity, or weight loss.

Drug therapy

Use drug therapy as an adjunct to behavior change only for patients who are at increased medical risk and who have not met reasonable weight loss goals after 6 months of behavior change strategies. Drug therapy results in a net weight loss of 4 to 22 pounds, with most weight loss occurring within the first 6 months of treatment. See **Table 6** for FDA-approved weight loss drugs. The safety and effectiveness of these medications have not been established for use beyond 2 years. 4

Weight loss drugs may have serious adverse effects; prescribe them with caution (**Table 6**). Before prescribing, talk to your patient about adverse effects, lack of long-term safety and effectiveness data, and the temporary nature of weight loss achieved by medications. ¹⁶ Sibutramine is contraindicated in many patients, ^{7,24} and some studies have raised safety concerns with both sibutramine^{25,26} and orlistat. ^{27,28} Closely monitor patients on drug therapy. Not every patient will respond to drug therapy. Initial non-responders are unlikely to respond even with an increase in dose. ⁷

Diethylpropion, mazindol, benzphetamine, phendimetrazine, and phentermine are still on the market for short-term use. Two appetite-suppressant medications, fenfluramine and dexfenfluramine, were withdrawn from the market in 1997 after being linked to the development of valvular heart disease and primary pulmonary hypertension. The possibility that phentermine may be associated with primary pulmonary hypertension cannot be ruled out.²⁴

Drugs that may induce weight gain	Drugs that are weight-neutra or promote weight loss
Diabetes drugs	
Insulin, glipizide, glyburide, glimepiride, pioglitazone, rosiglitazone, nategline, repagline	Metformin,† acarbose, miglito pramlintide, exenatide, sitagliptin phosphate
Antidepressants	
SSRIs (initial weight loss, then weight gain), monoamineoxidase inhibitors, tricyclic antidepressants, mirtazapine, trazodone	Buproprion, venlaflaxine, nefazodone
Mood stabilizers	
Lithium, valproic acid Less wt gain: quetiapine Antipsychotic drugs	Lamotrigine, tiagabine, ziprasidone, aripiprazole
Clozapine, olanzapine, thioridazine/mesorizadine, sertindole, chlorpromazine, risperidone, haloperidol, fluphenazine Less wt gain: quetiapine	Molindone, ziprasidone
Anticonvulsants	
Valproic acid, gabapentin, carbamazepine, oxcarbamazepine	Topiramate, lamotrigine
Migraine prevention drugs	
Anticonvulsants and antidepressants (as above), beta-blockers	Topiramate, verapamil
Contraceptives and hormone re	eplacement therapy
Hormonal contraceptives (progestin-containing)	Barrier methods, copper IUD
Hormone replacement therapy (progestin-containing) Anti-inflammatory drugs	No alternative
Corticosteroids (oral)	NSAIDs, inhaled corticostero
Antihypertensive agents	TNOAIDS, IIIIIdied Corricosiero
Alpha- and beta-blockers	Thiazide diuretics, ACE inhibitors, angiotensin recept blockers (ARBs)
Antiretroviral therapy	
All agents	No alternatives
Allergy drugs	
Diphenhydramine	Inhaled corticosteroids
Thyroid drugs	

Herbal preparations and supplements are not recommended. They are unregulated and have potentially harmful and unpredictable effects. FDA consumer alerts have been issued against some herbs, including products containing ephedra, aristolochic acid, and herbal weight-loss tea.³⁰

Bariatric surgery

Bariatric surgery, including vertical-banded gastroplasty and Roux-en-Y gastric bypass, is an option for carefully selected patients who are at increased medical risk, and who have had no sustainable success with diet, exercise, and behavior modification. Recommendations for considering bariatric surgery vary. The National Heart, Lung and Blood Institute (NHLBI) recommends that surgery be considered for those with a BMI ≥35 with comorbidities or a BMI ≥40 regardless of the presence of comorbidities. The American College of Physicians recommends that surgery be considered for those with a BMI ≥40 with comorbidities. 6

An average weight loss of 20 kg (44 lbs) for surgically treated patients at 8 years of follow-up was observed in one study. ¹⁶ Obesity-associated conditions such as type 2 diabetes, dyslipidemia, hypertension, and obstructive sleep apnea are improved or reversed in the majority of patients. ^{31,32} Bariatric surgery is also associated with a reduction in mortality. ³¹

Bariatric surgery has significant risks. A recent report found the 30-day mortality rate to be 1.9%. In another study, nearly 40% of patients required re-admission or emergency department visits during the 6 months following bariatric surgery.³² Operative complications include anastomotic leak, subphrenic abscess, splenic injury, pulmonary embolism, wound infection, and stoma stenosis.⁷ Later complications include incisional hernias, gallstones, and dumping syndrome.¹⁶

If a patient is a potential candidate for bariatric surgery, discuss surgery-related issues, including long-term side effects and the need to alter one's eating habits after surgery. Refer potential candidates for surgery to a high-volume center with experienced bariatric surgeons, as mortality and complication rates decrease with the volume of procedures performed.¹⁶

Summary

More than half of all NYC adults are overweight or obese. Behavioral changes, including healthier eating and regular physical activity, are the cornerstone of any weight loss program. Primary care physicians can help patients adopt gradual lifestyle changes to lose weight, maintain weight loss, and reduce obesity-related illness and death. •

Drug	Dose (oral)	Average weight loss (drugs & lifestyle change combined)	Action	Serious Adverse Effects ^{33,34}	Contraindications ^{33,34}	Cost/month (range) ^{35,36}
Sibutramine Meridia	10 mg initially; may be increased to 15 mg or decreased to 5mg.	9.5 lbs over 2 years	Norepinephrine, dopamine, and serotonin reuptake inhibitor.	Increase in heart rate and blood pressure, potential for abuse/dependence.	Hypertension, CHD, CHF, arrhythmias, history of stroke, use of MAOIs, eating disorders, severe renal impairment, hepatic dysfunction, pregnancy, and breastfeeding.†	\$105-138
Orlistat [‡] Xenical	120 mg tid before meals	6.2–9.9 lbs over 1–2 years	Inhibits pancreatic lipases, decreases fat absorption.	Decrease in absorption of fat-soluble vitamins, cramping, intestinal discomfort, soft stool and anal leakage, and need to take a multivitamin. ³³	Chronic malabsorption syndrome, cholestasis, pregnancy, and breastfeeding. Because of possible drug interactions, patients on cyclosporine should take orlistat at least two hours before or after taking cyclosporine.†	\$225-289

^{*}Other drugs have been used for weight loss, but they are not approved by the FDA for that indication per se (i.e., off-label use).

There are many precautions not listed here. Consult product information for complete descriptions about dose, action, adverse effects, and contraindications.

[‡]60 mg capsule approved by FDA in February 2007 for over-the-counter sales.

Clinician Resources

National Heart, Lung, and Blood Institute

Obesity Education Initiative: www.nhlbi.nih.gov/about/oei/index.htm

Assessment and management of overweight and obese patients

(online course): obesitycme.nhlbi.nih.gov BMI calculator: www.nhlbisupport.com/bmi

Centers for Disease Control and Prevention

Physical activity resources for health professionals:

www.cdc.gov/nccdphp/dnpa/physical/health_professionals/index.htm

Nutrition resources for health professionals:

www.cdc.gov/nccdphp/dnpa/nutrition/health_professionals/index.htm

The Surgeon General's Call to Action to Prevent and Decrease Overweight and Obesity

www.surgeongeneral.gov/topics/obesity

National Guideline Clearinghouse

Dietary Guidelines for Americans, 2005

www.guideline.gov/summary/summary.aspx?doc_id=6417

North American Association for the Study of Obesity

Obesity, bias and stigmatization:

www.naaso.org/information/weight_bias.asp

American Society for Bariatric Surgery

Suggestion for the pre-surgical psychological assessment of bariatric surgical candidates:

www.asbs.org/html/pdf/PsychPreSurgicalAssessment.pdf

NYS Department of Health

Strategic plan for overweight and obesity prevention: www.nyhealth.gov/prevention/obesity/strategic_plan.htm

Motivational Interviewing Techniques for Clinicians www.motivationalinterview.org/clinical/whatismi.html

Dunn C, Rollnick S. Lifestyle Change (Rapid Reference series).

Chicago, IL: Mosby; 2003. National Weight Control Registry

Research Findings: www.nwcr.ws/research

Patient Resources

Shape Up New York (free family fitness classes at city parks) www.nyc.gov/html/doh/html/cdp/cdp_pan_programs_comm.shtml#shape

NYC DOHMH Fitness Resource Directories for Select Communities

East and Central Harlem: www.nyc.gov/html/doh/downloads/pdf/cdp/ cdp-resource-harlem.pdf

North and Central Brooklyn: www.nyc.gov/html/doh/downloads/ pdf/dpho/dpho-brooklyn-fitnessprog.pdf

South Bronx: www.nyc.gov/html/doh/downloads/pdf/cdp/ cdp-resource-sobronx.pdf

NYC DOHMH Bureau of Chronic Disease Prevention and Control www.nyc.gov/html/doh/html/cdp/cdp.shtml

NYC Department of Parks and Recreation

www.nycgovparks.org

Transportation Alternatives

Rides and Walks: www.transalt.org/info/ridesandwalks.html

President's Council on Physical Fitness and Sports

www.fitness.gov

Centers for Disease Control and Prevention

Overweight and obesity: www.cdc.gov/nccdphp/dnpa/obesity

Physical activity for everyone:

www.cdc.gov/nccdphp/dnpa/physical/index.htm

Nutrition for everyone:

www.cdc.gov/nccdphp/dnpa/nutrition/nutrition_for_everyone/index.htm

American Heart Association

800-242-8721 or www.americanheart.org

Physical activity calorie use chart:

www.americanheart.org/presenter.jhtml?identifier=756

American Diabetes Association 800-342-2383 or www.diabetes.org

National Weight Control Registry Success Stories: www.nwcr.ws/stories.htm

References Available Online: www.nyc.gov/html/doh/downloads/pdf/chi/chi26-4-ref.pdf

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Preventing and Managing Overweight and Obesity in Adults.

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Preventing and Managing Overweight and Obesity in Adults **CME Activity** 1. DM is a 52-year old woman who has had diabetes for 6 years. 4. DM is having trouble sticking to an exercise plan. Her doctor She is 5'6", weighs 200 pounds, and has a BMI of 32kg/m². should support this lifestyle change by all of the following Her last A1C was 9.4%. Of the several medications she takes EXCEPT: for her diabetes, all can cause weight gain EXCEPT: A. Helping her identify and set small, achievable goals for A Insulin physical activity. B. Recommending a walking buddy or group. B. Glipizide C. Pioglitazone C. Discussing potential barriers to exercising and working D. Metformin with her to address those barriers. D. Telling her the best thing for her to do is join a avm and 2. DM eats at a fast-food restaurant 5 times a week, drinks get vigorous exercise such as aerobics. 16 oz of juice for breakfast, and has no time to exercise. All 5. It is important to discuss AB's weight status with sensitivity of the following changes can help improve her weight and and attention to potential stigma. His primary care physician health EXCEPT should do all of the following EXCEPT: A. Limiting fast food, deep-fried foods, and high-fat snacks. A. Weigh AB in a private setting without judgment B. Drinking water, seltzer, or 1% or skim milk instead of nonmailing address, telephone number, and e-mail address. PLEASE PRINT LEGIBLY. or comment diet soda, fruit drinks and juices, and high-fat milk. B. Use a large cuff, a large gown, and a scale that C. Getting off the bus or subway a stop or two early and accommodates more than 300 pounds. walkina. C. Tell AB that his fatness is unacceptable and instruct him D. Cooking with partially hydrogenated oils instead of on setting behavioral goals. canola or olive oil. D. Use empathic, interactive communication to help AB identify 3. AB is a 38-year-old man with diabetes, heart disease, and and set manageable goals for diet and physical activity. sleep apnea. He has a BMI of 42kg/m². All of the following 6. How well did this continuing education activity achieve its are appropriate for the management of his obesity EXCEPT: educational objectives? A. Developing a weight loss plan emphasizing healthy ☐ A. Verv well ☐ B. Adequately ☐ C. Poorly eating and physical activity. PLEASE PRINT LEGIBLY. B. Immediately starting medications such as orlistat or sibutramine because his obesity is so severe. Name _____ Degree _____ C. Setting a weight loss goal of 10% of total body weight Address _____ over 6 months City ______ State ____ Zip _____ D. Discussing bariatric surgery if, after a year of diet and exercise with intensive counseling, he is unable to meet Date _____ Telephone _____ can print out your certificate. his weight loss goals. E-mail address

Continuing Education Activity

This issue of City Health Information, including the continuing education activity, can be downloaded from the publications section at nyc.gov/health. To access City Health Information and Continuing Medical Education online, visit www.nyc.gov/html/doh/html/chi/chi.shtml.

Instructions

Read this issue of City Health Information for the correct answers to questions. To receive continuing education credit, you must answer 4 of the first 5 questions correctly.

- To Submit by Mail
- 1. Complete all information on the response card, including your name, degree,
- 2. Select your answers to the questions and check the corresponding boxes
- on the response card. 3. Return the response card (or a photocopy) postmarked **no later than**
- May 31, 2008. Mail to:

CME Administrator, NYC Dept. of Health and Mental Hygiene, 2 Lafayette, CN-65, New York, NY 10277-1632.

To Submit Online

Visit www.nyc.gov/html/doh/html/chi/chi.shtml to submit a continuing education test online. Once logged into NYC MED, use the navigation menu in the left column to access this issue of City Health Information. Your responses will be graded immediately, and you

Continuing Education Activity

Preventing and Managing Overweight and Obesity in Adults

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CITY HEALTH INFORMATION

APRIL/MAY 2007 VOL. 26(4):23-30

Objectives

At the conclusion of the activity, the participants should be able to:

- 1. Identify and manage patients who are overweight or obese.
- 2. Counsel patients on lifestyle modification.

Accreditation

The DOHMH is accredited by the Medical Society of the State of New York to sponsor continuing medical education for physicians. The DOHMH designates this educational activity for a maximum of 1 *AMA PRA Category 1 Credits*TM. Each physician should claim only those hours of credit that were spent on the educational activity.

Participants are required to submit name, address, and professional degree. This information will be maintained in the Department's CME program database. If you request, the CME Program will verify your participation and whether you passed the exam.

We will *not* share information with other organizations without your permission, except in certain emergencies when communication with health care providers is deemed by the public health agencies to be essential or when required by law. Participants who provide e-mail addresses may receive electronic announcements from the Department about future CME activities as well as other public health information.

Participants must submit the accompanying exam by May 31, 2008.

CME Activity Faculty:

Diana K. Berger, MD, MSc; Karen K. Lee, MD, MHSc; Lynn D. Silver, MD, MPH

All faculty are affiliated with the New York City DOHMH, Division of Health Promotion and Disease Prevention.

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How Many Calories Do People Need Each Day?

Most adults need about 2,000 calories a day.

Document 33-15

The exact number depends on a person's sex, age, and physical activity level, as shown in the table.

Eating or drinking more calories than the body uses causes weight gain – which can lead to obesity, diabetes, and heart disease.

Most people underestimate the calories they consume, especially for less-healthy items. As a result, it is easy to take in too many calories without realizing it. For example, some large sodas have as many as 600 calories. Some main dishes may contain 1600 calories - about three quarters of the calories most adults should eat in a whole day. Just 100 extra calories a day leads to 10 pounds of extra weight

To learn more about smart food choices, enter your age, sex and activity level in the My Pyramic Plan at www.mypyramid.gov.

Recommended Daily Calorie Intake						
	Ma	Females Activity level*				
	Activity level*					
Age	Sedentary	Moderate	Sedentary	Moderate		
C 42.3	1000	1000	345 T000	1000		
3	1000	1400	1000	1200		
4.5	1200	1400	1200	1400		
5	1400	1600	1200	1400		
7	7400	1600	1,200	1600		
8	1400	1600	1400	1600		
in ever break	1600	1800	1400	1600		
10	1600	1800	1400	1800		
11 %	1800	2000 :-	1600	1800		
12	1800	2200	1600	2000		
13	2000	2200	> 1600	. 2600		
14	2000	2400	1800	2000		
15	2200	2600	1800	2000		
16-18	2400	2800	1800	2000		
19-20	2600	2800	2000	2290		
21-25	2400	2800	2000	2200		
26-40	2400	2600 ->	1800	2000		
41-45	2200	2600	1800	2000		
46-50	2200	2400	1800	2000		
51-60	2200	2400	1600	1800		
61-65	2000	2400	1600	1800		
66 and up	2000	2200	1600	1800		

^{*} Sedentory means less than 30 minutes of moderate physical activity per day; most New Yarkers, are secentary. Moderate means 30 to 60 min sites a day of moderate physical activity. People who get 60 or more minutes a day of moderate physical activity should consume more calories (see www.my.gyramid.gov).

Table adapted from MyPyromid Food Intake Pattern Calorie Levels, USDA, April 2005.



N Y C of REALTH and MENTAL, HYGENE Health Michael R. Bloomberg, Wayor Thomas S. Frieden, MD, MPH, Commiss

